OmniPod®

Insulin Management System

Model: **UST400**

User Guide

Contacts and Important Information

Use the spaces below to record important health and product information.

Doctor

Name

Address

Telephone and Fax

Email Address

Nurse/Educator

Name

Address

Telephone and Fax

Email Address

Health Insurance

Name

Address

Telephone Number(s)

Policy Number

Pharmacy

Name

Address

Telephone and Fax

Email Address

OmniPod System Start Date: _____

PDM Model UST400 Serial Number: _____

Emergency Services:
Dial 911 (USA only; not available in all communities)

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9 Oak Park Drive, Bedford, MA 01730

Customer Care (24 hours/7 days): 800-591-3455
When calling from outside the United States: 781-457-5098

Customer Care Fax: 877-467-8538

Web site: MyOmniPod.com

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Introduction

About This User Guide

Symbols

Symbol	Term	Meaning
	Warning	Describes potential serious adverse reactions, or indicates conditions that could cause death or serious injury.
	Caution	Caution: Consult accompanying documents.
	Note	Provides helpful information.
	Tip	Offers a suggestion for successful use of the OmniPod® Insulin Management System.

This *User Guide* is intended for use only with PDM model UST400. To learn which version of the PDM you have, turn it over. On the back of the PDM, look for "UST400." If you see it, this is the correct *User Guide*. If you do not see "UST400" on the back of the PDM, please call Customer Care.

This *User Guide* is periodically updated. Visit the Customer Care section of MyOmniPod.com to see the most recent version and to find other helpful information.

Users should wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

Reminder: Users should activate the PDM periodically to confirm that there are no alerts or alarms that require a response.

NOTE Screen displays shown in this *User Guide* are for illustrative purposes only and should not be considered suggestions for user settings. Consult with your healthcare provider to determine the appropriate settings for you.

Conventions and Terms

Convention/Term	*Meaning*
Bold	Names of buttons, soft keys, menus, and screens are in **bold**.
Italics	Words in *italics* are defined in the Glossary at the end of this *User Guide*.
Press	Press and release a button or soft key.
Hold	Keep pressing a button until its function is complete.
Menu	A list of options on the PDM. Options allow you to perform tasks.
Screen	Displays programming, operating, and alarm/alert information.
Button	A physical button on the PDM, such as the **Home/Power** button.
Icon	An image on the PDM screen that indicates a menu option or item of information. A table of screen icons appears in the Appendices.
Soft keys	A row of three unlabeled buttons on the PDM whose label or function appears on the screen directly above the button. The label changes depending on the task you are performing.

Important Information

US Federal law restricts this device to sale by or on the order of a physician.

Indication

The OmniPod® Insulin Management System is intended for *subcutaneous* (below the skin) delivery of *insulin* at set and variable rates for the management of *diabetes mellitus* in persons requiring insulin and for the quantitative measurement of glucose in fresh whole capillary blood (*in vitro*) from the finger.

The glucose measurements should not be used for the diagnosis of or screening for diabetes. The PDM glucose meter is intended for single-patient use and should not be shared.

Abbott FreeStyle® test strips are used with the built-in FreeStyle meter for the quantitative measurement of blood glucose in fresh whole capillary blood from the finger, upper arm and palm. Abbott FreeStyle Control Solutions are used to verify that the meter and test strips are working together properly and that the test is performed correctly.

Contraindications

Insulin pump therapy is NOT recommended for people who are either:

- Unable to perform at least four (4) *blood glucose* tests per day
- Unable to maintain contact with their *healthcare provider*
- Unable to use the System according to instructions

Do not use the integrated FreeStyle Blood Glucose Monitoring System for:

- Testing on newborns
- Testing arterial blood
- Diagnosing of or screening for diabetes mellitus

The OmniPod System should NOT be used in a hyperbaric chamber as there is a potential for an explosion. There are active electronics inside the Pod and PDM, and a hyperbaric chamber has high concentrations of oxygen.

The OmniPod System is designed to use rapid-acting U-100 insulin. The following U-100 rapid-acting insulin analogs have been tested and found to be safe for use in the Pod: Novolog®/NovoRapid®, Humalog®, or Apidra®. Novolog® is compatible with the OmniPod System for use up to 72 hours (3 days). Before using a different insulin with the OmniPod System, check the insulin drug label to make sure it can be used with a pump. Refer to the insulin labeling and follow your healthcare provider's directions for how often to replace the Pod.

Not recommended for individuals with hearing loss. Always verify ability to hear Pod/PDM alerts and alarms.

The Pod and PDM may be affected by strong radiation or magnetic fields. Before having an X-ray, MRI, or CT scan (or any similar test or procedure), remove your Pod and put it and the PDM outside the treatment area. Check with your healthcare provider for Pod removal guidelines.

The glucose meter and lancing device are for single-patient use. Do not share the device with anyone including other family members. Do not use on multiple patients.

Parts of the device are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

If you are unable to use the System according to instructions, you may be putting your health and safety at risk. Talk with your healthcare provider if you have questions or concerns about using the System properly.

Please read all the instructions provided in this *User Guide* and practice the blood glucose testing procedures before using the System. Monitor your blood glucose with the guidance of your healthcare provider. Undetected hyperglycemia or hypoglycemia can result without proper monitoring.

This device is intended for self-testing by the user.

If you are having symptoms that are not consistent with your blood glucose test and you have followed all instructions described in this *User Guide*, call your healthcare professional.

n Your Role: Safely Using the OmniPod System

Pump therapy requires substantial caregiver involvement, especially among children. Work with your healthcare provider to establish diabetes management guidelines and settings that best fit your, or your child's, needs. These may include:

Insulin-to-Carbohydrate (IC) Ratio: Number of grams of carbohydrate covered by one unit of insulin. For example, if your *insulin-to-carbohydrate ratio* is 1:15, then you need to deliver one unit of insulin to cover every fifteen grams of carbohydrate you eat.

Correction or Sensitivity Factor: How much one unit of insulin will lower blood glucose. For example, if your *sensitivity factor* is 50, one unit of insulin will lower your blood glucose by 50 mg/dL.

Target Blood Glucose Value: The blood glucose level you want to achieve. For example, you may want to keep your blood glucose close to 100 mg/dL.

Duration of Insulin Action: The length of time that insulin remains active and available in your body after a correction or meal bolus.

Your individual needs influence the initial settings you and your healthcare provider will enter into the Personal Diabetes Manager (PDM) during setup (see Chapter 2, Getting Started).

Your healthcare provider must help you enter these initial settings. Soon you will enter and change your own settings with confidence and ease. The OmniPod System is more user-friendly than most electronic devices you use every day. In fact, technology is what makes the OmniPod System so easy to use.

Your healthcare provider is a valuable resource. You will rely on him or her for a lot of critical information about your OmniPod System, especially during the first few weeks and months. When you have questions about diabetes management after starting on the OmniPod System, do not hesitate to talk with your healthcare provider. For nonmedical emergencies or for technical questions about your OmniPod System setup or operation, you can call Customer Care 24 hours a day, 7 days a week.

Customer Care (24 hours/7 days): 800-591-3455
When calling from outside the United States: 781-457-5098

Customer Care Fax: 877-467-8538

Web site: MyOmniPod.com

Your healthcare provider will give you all the tools and training you need to be successful with the OmniPod Insulin Management System. However, in the end, your success depends on YOU. You must become actively involved in your own diabetes management to enjoy the outstanding control, freedom, and flexibility that is possible with the OmniPod System.

Being actively involved means:

- Frequently monitoring blood glucose levels
- Learning how to operate your OmniPod System and practicing proper techniques
- Visiting your healthcare provider

Do NOT attempt to use the OmniPod® Insulin Management System before you receive training from your healthcare provider. Inadequate training could put your health and safety at risk

CHAPTER 1

Your New OmniPod Insulin Management System

Insulin Delivery with the OmniPod System

The OmniPod® Insulin Management System is an innovative continuous insulin delivery system that provides all the proven benefits of *continuous subcutaneous insulin infusion (CSII)* therapy in a way no conventional insulin pump can. The System's innovative design and features allows you to live your life—and manage your diabetes—with unprecedented freedom, comfort, convenience, and ease.

The long-term health benefits of better blood glucose control are well known. Maintaining near-normal blood glucose levels can help you live a longer, healthier life with fewer diabetes-related complications. The OmniPod System also has many practical, everyday benefits, including convenience, freedom, flexibility, and ease of use.

Continuous insulin delivery most closely mimics the insulin release of a healthy pancreas. Since the landmark 10-year Diabetes Control and Complications Trial (DCCT), the long-term health benefits of maintaining near-normal blood glucose levels have been widely recognized.

Continuous *insulin* delivery at preset rates eliminates the need for injections and the interruptions that come with them. In addition, with the OmniPod System, insulin delivery can be changed with the press of a button to adapt to snacks or unexpected changes in daily routine. The OmniPod System is a great option for people with diabetes who require insulin.

The OmniPod System works much like the pancreas of a person without diabetes by delivering insulin in two ways:

- A small, constant, background supply of insulin (called a *basal rate*) is delivered automatically at a programmed rate, all day and night.
- An extra dose of insulin (called a *bolus*) can be delivered when you need it to match the *carbohydrates* in a meal or snack or to correct a high blood glucose.

1 Your New OmniPod Insulin Management System

How Does the OmniPod System Work?

The Pod is a small, lightweight, self-adhesive device that you fill with insulin and wear directly on your body. The Pod delivers precise, personalized doses of insulin into your body through a small flexible tube (called a *cannula*), based on instructions that you program into its wireless companion, the Personal Diabetes Manager. The cannula is inserted only once with each Pod.

The Personal Diabetes Manager (PDM) is a wireless, handheld device that:

- Programs the Pod with your personalized insulin-delivery instructions
- Wirelessly monitors the Pod's operation
- Includes a FreeStyle® blood glucose meter

With just two parts, you'll enjoy all the functionality and benefits of continuous insulin delivery and blood glucose monitoring. Plus you'll enjoy the safety, convenience, and freedom of:

No tubing

There is no tubing connecting the Pod to the PDM. You wear the Pod comfortably and discreetly under your clothes. You can carry the PDM separately in a backpack, briefcase, or purse. With the OmniPod Insulin Management System, you don't have to worry about snagging, tangling, or feeling tethered by tubing.

Suggested bolus calculation

Calculating bolus doses has never been easier. After you check your blood glucose, enter the carbs for your snack or meal. Based on your individual settings, the System displays a suggested bolus dose. You can accept the suggestion, change it, or cancel it.

Reference food library and carb presets

To make carbohydrate counting easier, the OmniPod System includes a reference food library. You can look up the carbs and other values for many standard food items. Foods are organized alphabetically and by category.

You can also enter your own favorite foods, snacks, or entire meals as "carb presets." Presets contain the grams of carbohydrate in the food item or meal. Next time you eat this same food, you don't have to count the carbs; just select your carb preset and the System does the calculating for you. The System stores up to 36 carb presets.

Automated cannula insertion

With the OmniPod System, you don't have to insert the *infusion set* manually or carry around a separate inserter. You simply press a button on the PDM and the Pod's automated insertion system safely and consistently inserts the cannula beneath the skin, virtually pain free. It then begins delivering insulin according to your programmed basal rate.

A fully-integrated design with blood glucose monitoring

With a fully integrated two-part design, there's no need to carry separate infusion sets, reservoirs, or inserters. It's all integrated into the Pod. With the PDM, you can check your blood glucose level using FreeStyle® blood glucose test strips, but without the hassle of carrying a separate blood glucose meter.

If you prefer to use another blood glucose meter, you can enter the readings manually into the PDM.

Record keeping

Another convenient part of the OmniPod System is record keeping. Paper charts are useful, but sometimes they can be inconvenient to carry or use. The data storage system in the Personal Diabetes Manager (PDM) displays up to 90 days' worth of information. This includes blood glucose readings, basal rates and bolus doses, carbohydrates, and alarms.

Personalizing your System

You can personalize your OmniPod System in other ways, too:

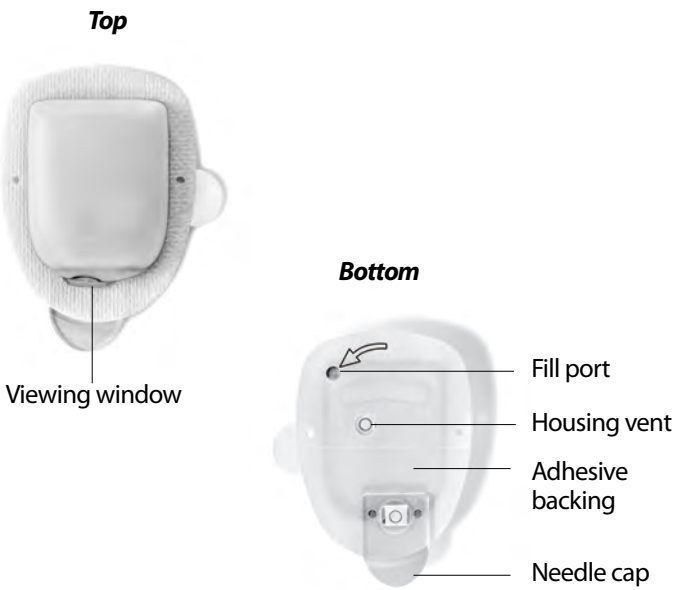
- Enter and name basal programs
- Name and save temporary basal presets
- Add your own customized reminders
- Enter your name, phone number, doctor's name and number, and other emergency information

1 Your New OmniPod Insulin Management System

The Pod

The **Pod** (Figure 1-1) is applied to your skin with an adhesive, similar to an adhesive bandage.

Figure 1-1

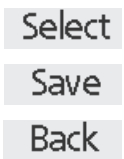


The Personal Diabetes Manager

All Pod operations are programmed and controlled through the **Personal Diabetes Manager** (**PDM**; Figure 1-2).

Figure 1-2

Buttons that program and control the OmniPod System

Button	*Action*
Home/ Power	Pressing and holding turns the PDM on and off. When the PDM is on, pressing this button (quickly/briefly) displays the **Home** screen, from which you can choose a menu item or view the **Status** screens (shown later in this chapter).
Up/Down Controller	Pressing and releasing scrolls through a list of available menu options or numbers, so you can pick the one you want. Holding the button scrolls faster.
Soft Keys 	Soft key labels and functions depend on the menu or screen you are viewing. The label appears on the screen directly above the physical button you press. **Select**, **Save**, and **Back** are just three examples of the soft key labels on your PDM.

Button	*Action*
User Info/ Support	Pressing opens a **User Info/Support** screen that displays additional information about the current screen you are viewing. The **User Info/Support** icon appears when additional information can be viewed. It may be displayed at the top of the screen, to the right of an event detail (such as a suggested bolus), or to the right of a record item (such as a BG history record). (See "Personal Diabetes Manager Icons" in the Appendix). In addition, pressing and holding this button for 2 seconds enables a "bright mode" on the PDM screen.

Primary screens

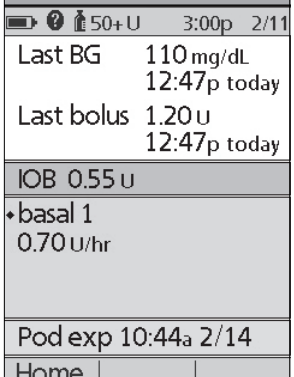
Messages on the screen either:

- Let you identify your PDM
- Tell you how the System is operating
- List menu choices
- Explain how to perform certain tasks

The System's primary screens are the **ID** screen (Figure 1-3), the **Status** screen (Figure 1-4), and the **Home** screen (Figure 1-6 on the next page).

Figure 1-3

Figure 1-4



ID screen

The System displays an **ID** screen to make the PDM easy to identify when you first turn it on. You can personalize the **ID** screen by adding your name and choosing its color. (See , for details on customizing your PDM.) You must acknowledge the **ID** screen before you can use the PDM. It is important that you always identify the PDM as yours before you use it.

Status screen

Lists the System's current operating status (Figure 1-4).

From top to bottom, the **Status** screen displays:

- Current date and time
- Battery life remaining
- Insulin remaining
- Time, date, and result of last blood glucose checked or entered manually
- Time, date, and total amount of last bolus delivered
- Amount of Insulin on Board (IOB) will be displayed on **Status** screen (if calculator in use)
- Name and rate of active basal program or temp basal program
- "Ext bolus," the amount of insulin, and the delivery time remaining if an extended bolus is being delivered
- "INSULIN SUSPENDED" if insulin delivery has been suspended
- Time and date of when the Pod will expire

NOTE If a Pod has not yet been activated (during Pod changes), the screen displays "No active Pod. Would you like to activate a Pod now?" (See Chapter 5, Using the Pod, for details on activating a Pod.)

Status support screen

From the **Status** screen, press the **User Info/Support** button to see details about the current **insulin on board (IOB)** in your body (Figure 1-5). See page 31, for additional information describing insulin on board (IOB).

Figure 1-5

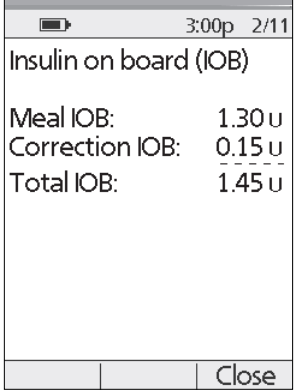
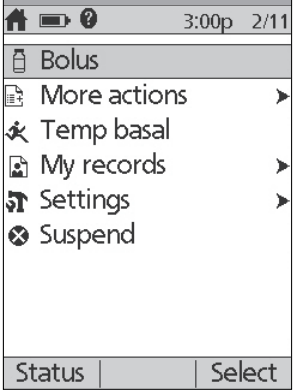


Figure 1-6



Home screen

Lists all the major menus (Figure 1-6).

- **Bolus** menu to deliver bolus doses
- **More actions** menu to change the Pod, manually enter blood glucose readings, and assign and edit tags for BG readings that are less than 2 hours old.
- **Temp basal** menu to deliver temporary basal rates (This submenu does not appear if temp basal is turned **Off** in **Settings**.)
- **My records** menu to review insulin delivery, blood glucose history, alarm history, carb history, and personal user information
- **Settings** menu to edit, enter, and name basal programs, temp basal, carbohydrate and bolus presets, and to customize System settings
- **Suspend** menu to suspend, cancel, or resume insulin delivery programs

NOTE You can go to the **Status** screen at any time by pressing **Status** from the **Home** screen.

n Safety Features

The OmniPod System's state-of-the-art design includes the latest safety technology. Its built-in safety features include:

Automatic priming, safety checks, and insertion

Every time you activate a new Pod, the System automatically primes and performs a safety check on the Pod, then inserts and primes the cannula (see Chapter 5, Using the Pod). Microprocessor technology makes it possible to complete thousands of safety checks in only a few seconds.

The OmniPod System also performs safety checks on the PDM. If it detects any problems in the PDM or the Pod—or in communication between them—it informs you with beeps and on-screen messages.

Occlusion detection

An occlusion is a blockage or interruption in insulin delivery. If the OmniPod System detects an occlusion, it sounds a hazard alarm and prompts you to deactivate and change your Pod (see Chapter 5, Using the Pod).

A hazard alarm sounds when an average of 3 to 5 units of missed insulin occurs. This table depicts occlusion detection for 3 different situations when using U100 insulin (Table 1). If an occlusion is cleared, a volume of insulin could be released. That volume would not exceed 3.9 U.

If an occlusion is detected during an immediate bolus, the Pod will alarm at the conclusion of the bolus.

Table 1:

	Minimum time	Typical time	Maximum time
5.00 U Bolus	**200 seconds**	**202 seconds**	**300 seconds**
1.00 U/hr basal	**2.4 hr**	**3.7 hr**	**5.0 hr**
0.05 U/hr basal	**48 hr**	**74 hr**	**80 hr** (Pod expiration)

At very low flow rates checking your blood glucose frequently may give you an early indication of an occlusion (refer to Chapter 9, page 115).

Alerts and alarms

For your safety, the OmniPod System provides a range of alerts and alarms to tell you that your attention is needed, or to warn you of hazardous situations.

Confirm on **ID** screen - alerts/alarms do not show on PDM until after **ID** screen is confirmed.

See Chapter 6, Using the Personal Diabetes Manager, for a description of notifications and how to set them. See Chapter 10, Alerts and Alarms, for a list of safety alarms built into the OmniPod System and how to respond to them.

CHAPTER 2

Getting Started

The OmniPod Starter Kit

Your initial shipment contains everything you need to begin using the OmniPod System.

If you are a first-time OmniPod System user, you need to meet with your healthcare provider for training and System setup before using it. To get a head start on learning about your new OmniPod System, review this *User Guide* and complete the Pre-Training section of OmniPod's online Interactive Training Program, found in the Customer Care section of MyOmniPod.com. If you have a basic understanding of the System in advance, you will get more out of your training sessions.

After you unpack the Starter Kit, use the "Contents" label on the sided of the box to make sure you have everything. Then complete the Warranty card and promptly mail it to us. Returning the card allows us to contact you with important product updates or Warranty information.

TIP You can also complete the Warranty form online at MyOmniPod.com.

WARNING Do NOT use the OmniPod® Insulin Management System until you have been trained by your healthcare provider. He or she will initialize the System based on your individual needs. Inadequate training or improper setup could put your health and safety at risk.

NOTE Prepare and keep an emergency kit with you at all times to quickly respond to any diabetes emergency. For details, see Chapter 9, Living with Diabetes.

Set Up the Personal Diabetes Manager (PDM)

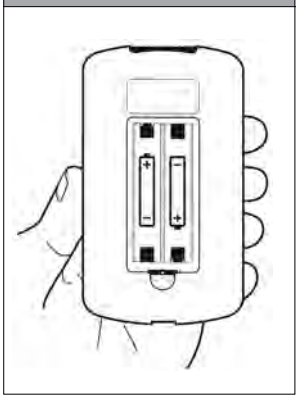
Chapter 6 describes the PDM options in detail. The instructions in this chapter are simplified to help you get started.

Turn on the PDM

1. Open the battery compartment on the back of the PDM by pushing the compartment latch and lifting upward (Figure 2-1 on the next page). No special tools are necessary.

Figure 2-1

Figure 2-2



2. Insert two (2) new AAA alkaline batteries into the compartment.

NOTE The diagram inside the compartment shows you which direction to insert the batteries (Figure 2-2).

Do not use any other type of batteries than AAA alkaline batteries to power the PDM. Never use old or used batteries; the PDM may not work properly.

3. Replace the battery door.
4. Turn the PDM face up. The PDM has begun to power on automatically.

n The Setup Wizard

The first time you turn on the Personal Diabetes Manager, the Setup Wizard comes on automatically. Although setup is easy with the Wizard, if you are a first-time user, your healthcare provider must guide you through the process. Setup takes only a few minutes and is easy to do:

- Use the **Up/Down Controller** buttons to increase or decrease a number, or to move up or down a list.

  NOTE Initial settings are "---" [blank] for target blood glucose value, insulin-to-carbohydrate ratio, correction factor, and duration of insulin action.

- Press the *Soft Key* labeled **Next**, **Select**, **Done**, or **Save** to continue to the next screen.
- Press **Back** to return to the previous screen.

  NOTE You can adjust these settings later as your needs change or as you fine-tune your OmniPod System.

To get started, press **Next** on the Wizard's Welcome Screen to begin setting up your PDM. It might be helpful to read each screen out loud as you proceed.

Enter your PDM ID

1. Use the **Up/Down Controller** buttons to scroll through the list of characters. An up-and-down-arrow symbol on the screen indicates the character you are changing.

2. Press the middle *Soft Key* (labeled with the right arrow) to move the underscore to the next character.
3. Enter each character one at a time. For example, if you want to enter your name, you might enter J, a, n, e, [space], S, m, i, t, h. (A blank character or space is the first and last option in the scrolling menu.)
4. Press **Next**.

Select the ID screen color

Use the **Up/Down Controller** buttons to choose a color, then press **Next**.

NOTE Your ID and the chosen color will be displayed on an identification (ID) screen that you must acknowledge every time you turn on the PDM. Always be sure you properly identify your PDM before using it.

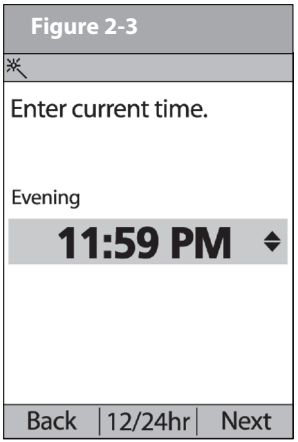
Set date and time

1. Use the **Up/Down Controller** buttons to increase or decrease the time. (Press **12/24hr** if you prefer a different time format.) Then press **Next** (Figure 2-3).

NOTE 12 Midnight – 5:59 AM: "Night"
6:00 AM – 11:59 AM: "Morning"
12 Noon – 5:59 PM: "Afternoon"
6:00 PM – 11:59 PM: "Evening"

On some screens, the time may show as "a" for "AM" and "p" for "PM".

Figure 2-3



2. Enter the current year, then press **Next**.
3. Choose the current month, then press **Next**.
4. Enter the current day of the month, then press **Next**.
5. Choose the date format you prefer, then press **Next**.
6. Press **Confirm**, to save the date and time settings (Figure 2-4 on the next page).

Figure 2-4

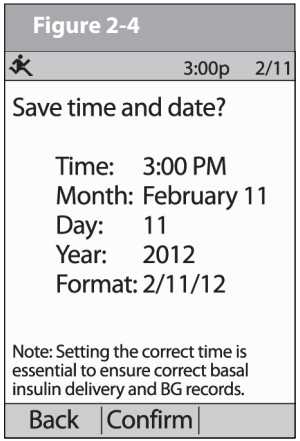


Figure 2-5

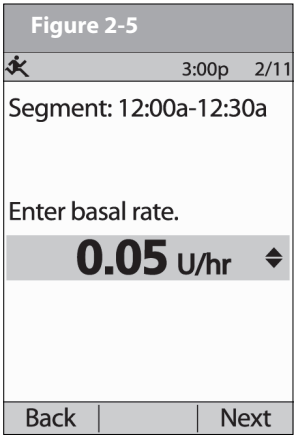
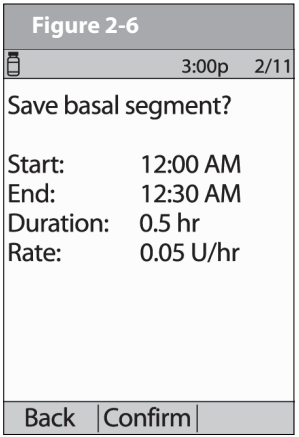


Figure 2-6



Enter basal settings

1. Choose a maximum *basal rate*, then press **Next**. (The default maximum basal rate is 3 U/hr.)
2. Enter initial basal rate that starts at midnight, then press **Next** (Figure 2-5).

   The initial basal program created with the Setup Wizard is named basal 1. You can change the name in the **Settings > Basal Programs** menu (see Chapter 3, Understanding and Adjusting Basal Rates).
3. Press **Confirm** to accept the basal program you have set (Figure 2-6).
4. Press **Done** to confirm the basal program shown on the screen. To add more *basal segments* to the program, or to change the rate shown, see Chapter 3, Understanding and Adjusting Basal Rates.
5. Press **Save** to accept the basal program you have set. To see the basal program as a list, press **List**. To return to the graphic view, press **Graph**.
6. Choose a *temporary basal* feature, then press **Next**. Choose **%** to show temporary basal rates as a percent increase or decrease of your current basal rate. Choose **U/hr** to show

temporary basal rates in units per hour. Or choose **Off** to turn off the temporary basal feature. For details about setting temporary basal's, see Chapter 3, Understanding and Adjusting Basal Rates.

You can add up to 7 basal programs and set 24 segments per program.

Enter blood glucose sound setting and BG goal

1. To set the sound for the blood glucose meter, choose **On** or **Off**, then press **Next**.
2. Use the **Up/Down Controller** buttons to enter the lower limit for your blood glucose (BG) goal, then press **Next**.
3. Enter the upper limit for your BG goal, then press **Next**.
4. Press **Save** to accept the BG goal.

Check with your healthcare provider before adjusting these settings.

Set the suggested bolus calculator

To set the *suggested bolus calculator* feature, choose **On** or **Off**, then press **Next**.

If the suggested bolus calculator is set to **On**, perform the following steps. If set to **Off**, you will be prompted to "Select bolus increment" and "Enter maximum bolus."

Enter target blood glucose value

1. Use the **Up/Down Controller** button to enter a *target blood glucose* (BG) value, then press **Next**.
2. Use the **Up/Down Controller** buttons to enter the "correct above" value or *correction threshold* (the BG value above which you want the PDM to suggest a *correction bolus*), then press **Next**.

If the suggested bolus calculator is **On**, a correction bolus will be suggested only when your BG is above the value shown in brackets on the screen.

3. To save the target BG value, press **Done**. To change these settings, select the segment you wish to change and press **Edit**.

   You can define up to 8 target BG time segments. To enter additional segments, choose **[add new]**, then:

   a. Press **New**.

   b. Enter a start time for the target BG segment, then press **Enter**.

   c. Enter an end time for the target BG segment, then press **Next**.

   d. Enter a target blood glucose value, then press **Next**.

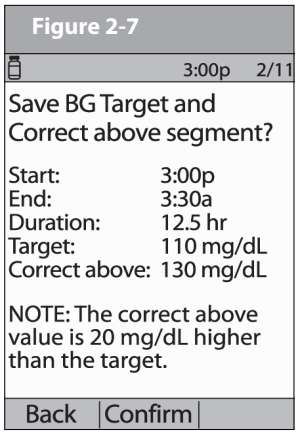
      Use the **Up/Down Controller** buttons to enter the "correct above" value or "correction threshold" (the BG value above which you want the PDM to suggest a correction bolus), then press **Next**.

e. Press **Confirm** to accept the target BG profile you have set (Figure 2-7).

f. When you have finished entering segments, press **Done**.

4. Press **Save** to accept the target BG profile you have set. To see the segments as a list, press **List**. To return to the graphic view, press **Graph**.

Figure 2-7



Enter minimum BG allowed for use in bolus calculation

1. Use the **Up/Down Controller** buttons to enter a minimum blood glucose value, below which the System will not calculate a suggested bolus. The values are in 1 mg/dL increments and range from 50 to 70 mg/dL.
2. Press **Next**.

Enter insulin-to-carbohydrate ratio

1. Use the **Up/Down Controller** buttons to enter your *insulin-to-carbohydrate ratio*, then press **Next**. (Insulin-to-carbohydrate ratio is the number of carbs covered by 1 unit of insulin.)
2. To save the ratio, press **Done**. To change the ratio, select the segment you wish to change and press **Edit**.

   You can define up to 8 insulin-to-carbohydrate time segments. To enter additional ratios, choose **[add new]**, then:

   a. Press **New**.

   b. Enter a start time for the segment, then press **Next**.

   c. Enter an end time for the segment, then press **Next**.

   d. Enter the insulin-to-carb ratio for the new time segment, then press **Next**.

   e. Press **Confirm** to accept the IC ratio you have set.

   f. To save the new ratio, press **Done**.
3. To see the ratios as a list, press **List**. To return to the graphic view, press **Graph**.
4. Press **Save** to accept the ratios you have set.

Enter correction factor

1. Use the **Up/Down Controller** buttons to enter how much one unit of insulin decreases your blood glucose, then press **Next**.
2. To save the *correction factor*, press **Done**. To change the factor, select the segment you wish to change and press **Edit**.

   You can define correction factors for up to 8 time segments. To enter additional correction factors, choose **[add new]**, then:

   a. Press **New**.
   b. Enter a start time for the segment, then press **Next**.
   c. Enter an end time for the segment, then press **Next**.
   d. Enter the correction factor, then press **Next**.
   e. On the next screen, review the segment to ensure it is correct, then press **Confirm**.
   f. To save the new correction factor segment, press **Done**.
3. To see the factors as a list, press **List**. To return to the graphic view, press **Graph**.
4. Press **Save** to accept the correction factors you have set.

Set reverse correction

1. To set reverse correction, use the **Up/Down Controller** buttons to choose **On** or **Off**, then press **Next**.

If you enter carbs and reverse correction is **On**, the System will subtract insulin from the suggested meal bolus to compensate for a low blood glucose (below the BG target you set). With reverse corrections **Off**, the System will not subtract insulin from the suggested meal bolus dose due to a low BG. Follow your healthcare provider's recommendation to set reverse correction **On** or **Off**.

Enter the duration of insulin action

1. Use the **Up/Down Controller** buttons to enter the *duration of insulin action* (how long insulin lasts in your body), then press **Next**.

The duration-of-insulin-action setting is used to calculate the amount of insulin on board (IOB) from a previous correction bolus or meal bolus when you use the suggested bolus calculator.

Select bolus increment and enter maximum bolus

1. Choose a bolus increment (how much each press of the **Up/Down Controller** buttons will increase or decrease a bolus amount)—either 0.05, 0.10, 0.50, or 1.00 units of insulin—then press **Next**.

2. Choose the maximum bolus you can give at one time, then press **Next**.

The maximum bolus default is 10 units. Check with your healthcare provider before adjusting these settings.

Set extended bolus doses

To set the units for an extended bolus dose, choose **%** for percent of the total bolus, or choose **Units** for units of insulin. To turn off the extended bolus feature, choose **Off**. Then press **Next**.

Set low reservoir advisory

1. Choose the level of insulin in the reservoir at which the PDM should give you an alarm. Choose from 10 to 50 units in 5-unit increments, then press **Next**.

Set Pod expiration notification

1. Choose the number of hours before a Pod expires when the PDM should give you a notification, then press **Next**. The values are in 1-hour increments and range from 1 to 24 hours. (The default is 4 hours.)

The PDM asks whether you want to activate a Pod.

- Press **Yes** if you are ready to activate a new Pod. See Chapter 5, Using the Pod, to learn how to activate a new Pod.
- Press **No** if you do not want to activate a Pod at this time. The PDM displays the **Home** screen.

You can press and hold the **Power** button to turn off the PDM at any time during setup. Otherwise, it turns off automatically after 5 minutes. If you do not complete the entire setup within 60 minutes, when you turn on the PDM again you will return to the beginning of the Setup Wizard.

Your healthcare provider will help you fill and apply your first Pod. The process is easy because on-screen messages walk you through every step. Please refer to Chapter 5, Using the Pod, for detailed instructions.

You may want to adjust the PDM screen time-out and backlight time-out. For more information on how to do this, see Chapter 6, Using the Personal Diabetes Manager.

Use the form at the end of this *User Guide* to write down all your settings from the Setup Wizard. If you ever need to reset or replace your PDM, having these settings handy will make setup very easy.

CHAPTER 3

Understanding and Adjusting Basal Rates

What Is a Basal Rate?

A basal rate is a small base or background amount of insulin that is delivered, at a preset rate, continuously for a specified period of time.

Even without eating, our bodies need a small, constant supply of insulin for normal daily living. In people without diabetes, the pancreas continuously delivers this basal insulin. For people using the OmniPod® Insulin Management System, the Pod mimics a healthy pancreas by delivering insulin at the rate that you've programmed into the Personal Diabetes Manager (PDM).

NOTE

Approximately 50% of a person's total daily insulin dose typically comes from basal insulin delivery; the remaining 50% typically comes from bolus doses (see Chapter 4, Understanding and Delivering Bolus Doses).

Personalized Basal Programs

Insulin needs vary throughout the day. Therefore, most people set their basal rates to deliver slightly more or less insulin at certain times. For example, one person may need to deliver a higher rate of insulin during the early morning and a lower rate during the late evening. A basal program describes the amount of insulin to be delivered during an entire 24-hour period.

A basal program contains at least one basal rate for the 24-hour period, but for most people it will be broken into several time segments, or basal segments, each delivering a different rate of insulin. A sample basal program with three basal segments might be:

12:00 am–8:00 am	0.60 U/hr	Between 12:00 am (midnight) and 8:00 am, the Pod delivers 0.60 units of insulin per hour.
8:00 am–3:00 pm	0.80 U/hr	Between 8:00 am and 3:00 pm, the Pod delivers 0.80 units of insulin per hour.
3:00 pm–12:00 am	0.70 U/hr	Between 3:00 pm and 12:00 am (midnight), the Pod delivers 0.70 units of insulin per hour.

3 Understanding and Adjusting Basal Rates

In addition to normal daily changes, insulin needs can vary with different routines or days of the week. For example, regular school or workday routines may differ from weekend routines, and insulin needs may differ, too. With your healthcare provider, you will decide on the basal rates that best match your lifestyle and insulin needs. You will enter at least one basal program (your Basal 1 Program) into your PDM during the setup process (see Chapter 2, Getting Started). You can add other programs later as you fine-tune your System settings or when your needs change.

You can also create temporary basal presets to use on occasions when you need to adjust your basal rate for a short period of time. See "Temporary Basal Rates and Presets" later in this chapter.

Create a basal program

The Personal Diabetes Manager can store up to 7 different basal programs. Each program can contain 24 rates, programmed in half-hour increments. Once you enter a basal program into the PDM, you only need to press a few buttons to pick the program you want. The Pod continues to deliver insulin at those rates until you change that program or switch to another one.

Check with your healthcare provider before adjusting these settings.

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
2. Choose **Basal programs** (Figure 3-1), then press **Select**.

Figure 3-1

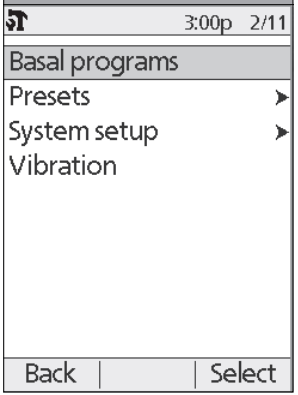
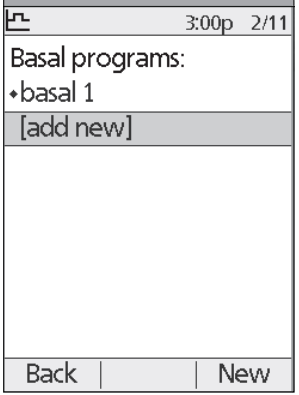


Figure 3-2



3. Choose **[add new]** (Figure 3-2), then press **New**.
4. To use the default naming system, simply press **Next**. The default naming system automatically assigns program names in numerical order, such as basal 1, basal 2, basal 3.

   If you want to give a different name to the program:

   a. Press the **Up/Down Controller** buttons to scroll through the list of characters. An up-and-down arrow symbol on the screen indicates the character you are changing.

b. Press the middle *Soft Key* (labeled with the right arrow) to move the underscore to the next character.

c. Enter each character one at a time. For example, if your weekend schedule is different from your weekday schedule, you might enter W, e, e, k, e, n, d (Figure 3-3). (A blank character or space is the first and last option in the scrolling menu.)

Figure 3-3

Figure 3-4

d. Press **Next**.

NOTE As a safety feature, the words "Invalid basal program name" (Figure 3-4) appear if the name you entered does not have at least one character or if the name is being used for another basal program. Capitals and lowercase letters are considered the same. Press **OK** to return to the previous screen and enter a different name.

5. Enter the rate, in U/hr, for the first basal segment (from 0.05 to the maximum you entered during setup), then press **Next**.
6. On the next screen, review the segment to ensure it is correct, then press **Confirm**.
7. Review the list showing your new basal program.

   To use the same basal rate for the entire 24-hour program, press **Done** and continue with step 7.

   Or, to add basal segments and rates (for example, a higher basal rate between 8:00 am and 3:00 pm):

   a. Choose an existing basal segment, then press **Edit**.

      Or, choose **[add new]**, then press **New**.

   b. Enter the start time (for example, 8:00 am), then press **Next**. Basal segments are in 30-minute increments.

   c. Enter the end time (for example, 3:00 pm), then press **Next**.

   d. Enter the rate for the new basal segment (for example, 0.80U/hr), then press **Next**.

NOTE Basal rates outside the changed segment do not change.

e. Repeat steps a–d for each new segment and rate you want, then press **Done**.

NOTE Press and hold the **Power** button to turn the screen back on. In some cases, if it has been less than 5 minutes since the screen timed out, pressing the **Power** button returns you to the same screen you were using. If it has been longer than 5 minutes, the PDM brings you to the **Status** screen.

8. Review the graph of the new basal program (Figure 3-5).
9. To see the program as a list, press **List** (Figure 3-6). To see the graph again, press **Graph**.

   The total daily basal that will be delivered is shown at the bottom of each "Basal programs" graph and list.
10. To add the program to the PDM's memory, press **Save**.

Repeat steps 1 through 9 (above) for each basal program (up to 7 programs) you want to create.

Figure 3-5

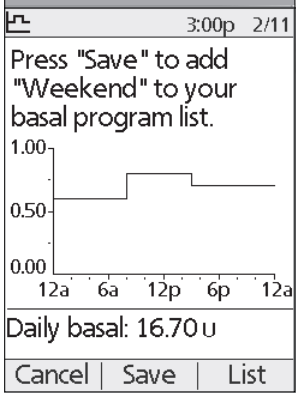


Figure 3-6

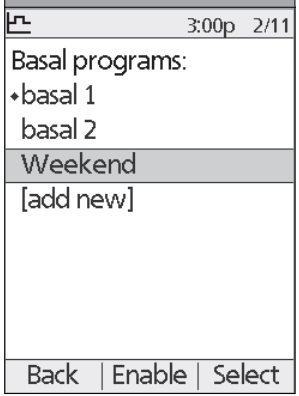
3:00p 2/11
Press "Save" to add "Weekend" to your basal program list.
Segment U/hr
12:00a - 8:00a 0.60
8:00a - 3:00p 0.80
3:00p - 12:00a 0.70
Daily basal: 16.70 u
Cancel Save Graph

Enable an existing basal program

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
2. Choose **Basal programs**, then press **Select**.

3. Choose the program you want from the list (Figure 3-7), then press **Enable**.

Figure 3-7



NOTE A diamond icon (u) appears next to the program that is active. You cannot select the active program to enable it, because it is already running.

4. Press **Enable** again to start the selected basal program. If a Pod is active, the PDM beeps to indicate that the chosen basal program is running.

NOTE As a safety feature, you cannot enable a new basal program while a temporary basal program is in process (see "Temporary Basal Rates and Presets" later in this chapter); you must first cancel the active temporary basal program.

Change, rename, copy, or delete a basal program

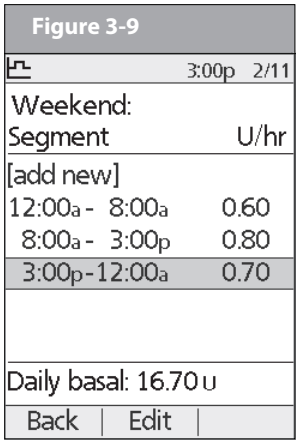
1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
2. Choose **Basal programs**, then press **Select**.
3. Choose a program from the list, then press **Select**.

To view the segments of the basal program

1. Choose **View**, then press **Select** (Figure 3-8).

Figure 3-8

Figure 3-9



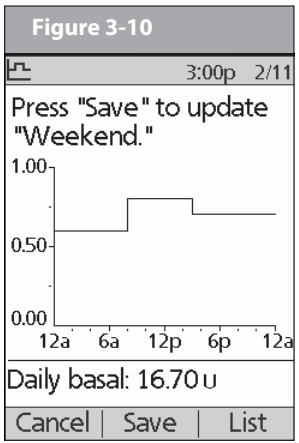
To edit or add a segment or rate in the basal program

1. Choose **Edit**, then press **Select**.

NOTE As a safety feature, you must suspend insulin delivery before editing an active basal program (see Chapter 5, Using the Pod). Remember to resume delivery after the edits are made.

2. Choose the segment to change, then press **Edit** (Figure 3-9). Or, choose **[add new]**, then press **New**.
3. Enter a start time for the segment you want to change, then press **Next**.
4. Enter an end time for this segment, then press **Next**.
5. Enter a basal rate for the new segment, then press **Enter**.
6. Review this new segment for accuracy, then press Confirm.
7. To save the newly entered segment into the basal program, press **Save** (Figure 3-10). If you want to make additional edits, repeat steps 2–5.

Figure 3-10



8. To see the program as a list, press **List**. To see the graph again, press **Graph**.

To rename a basal program

1. After choosing a program from the list, choose **Rename**, then press **Select**.
2. Press the **Up/Down Controller** buttons to enter the characters that spell out the new name you want. Press the middle soft key (labeled with the right arrow) to move the underscore to the next character, then press **Save**.

To copy a basal program

1. After choosing a program from the list, choose **Copy**, then press **Select**.
2. Press the **Up/Down Controller** buttons to enter the characters that spell out the name you want for the copied file. Press the middle soft key (labeled with the right arrow) to move the underscore to the next character, then press **Next**.
3. To use the same basal program for the entire 24-hour period, press **Save**.

To edit or add segments to the newly copied basal program, follow the steps under "To edit or add a segment or rate in the basal program" earlier in this chapter.

Instead of suspending, changing, and then resuming the active basal program, try this: Copy the active program, rename it, make the changes, save it, then enable it.

To delete a basal program

1. After choosing a program from the list, choose **Delete** and then press **Select**.
2. Press **Delete** to permanently delete the program.

As a safety feature, you cannot delete the active basal program.

n Temporary Basal Rates and Presets

What is a temporary basal rate?

A temporary basal rate lets you adjust your basal rate for a predetermined period of time.

On occasion, you may need to change the active basal rate for only a short time. For example, if you are going cross-country skiing for several hours, you may want to lower the basal rate during and after you exercise. This is called a "one-time temporary basal rate."

Some temporary changes are easy to predict and respond to. They happen routinely and you may know from experience how they affect your insulin needs. For example, you might take the same exercise class twice a week for a few weeks or months, or join a summer soccer league. For women, a monthly hormonal change that affects blood glucose is an example of predictable change. To easily handle predictable, short-term changes, you can "preset" a temporary basal rate, so it is ready whenever you need it. The PDM can remember up to 7 temporary basal presets.

3 Understanding and Adjusting Basal Rates

You can set a temporary basal rate for a duration of 30 minutes to 12 hours. Once the time limit is reached, the Pod automatically returns to the active basal program. Pod and PDM do not need to be close to each other.

When using units per hour, the OmniPod System allows you to set temporary basal rates from 0.0 U/hr, up to your max basal rate. When using percent rate, you can set temporary basal rates from Off to +95% of your active rate, as long as the temporary rate is less than or equal to your max basal rate. Another limit on the temp basal rate when configured in % is that the rate cannot be decreased such that the resultant flow rate will be less than 0.05U/hr. Example – if flow rate is 0.10U/hr, you can't create a temp basal decrease of 60%.

See the sections below on creating, enabling, cancelling, and changing temporary basal presets.

Enable a one-time temporary basal rate

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Temp basal**, then press **Select**.
2. If you have created temp basal presets, choose **[enter manually]** from the list, then press **Select**.

   If you have not created any temp basal presets, the PDM skips this step.
3. Choose **Increase** or **Decrease** your basal rate, then press **Next** (Figure 3-11).
4. Enter the temporary basal rate, depending on how you choose to show the rates or percent change, then press **Enter** (Figure 3-12 shows an example of a temporary basal increase. In this example, 25% MORE insulin will be delivered).

Figure 3-11

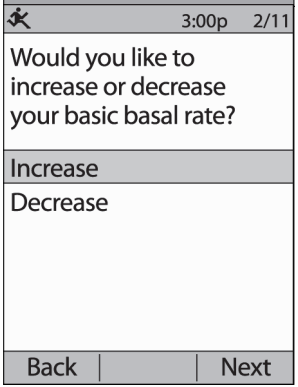
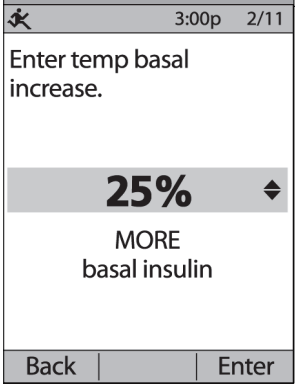


Figure 3-12



NOTE During initial setup, you and your healthcare provider either turned **Off** temporary basal rates, or chose to show the rates as **%** or **U/hr**. To change this setting, see Chapter 6, Using the Personal Diabetes Manager.

5. Enter the duration for the temporary rate, then press **Enter** (Figure 3-13 on the next page).

6. Press **Confirm** to start the temporary basal rate shown on the screen (Figure 3-14 – in this example, 25% more basal insulin will be delivered for 0.5 hours). The Pod beeps to indicate that the temporary basal rate is running.

Figure 3-13

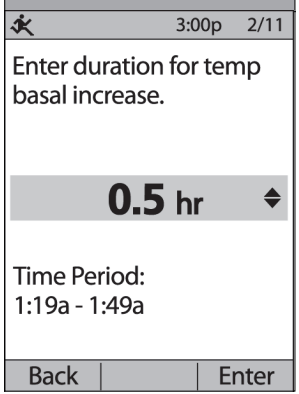
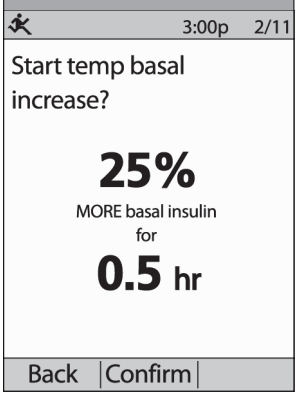


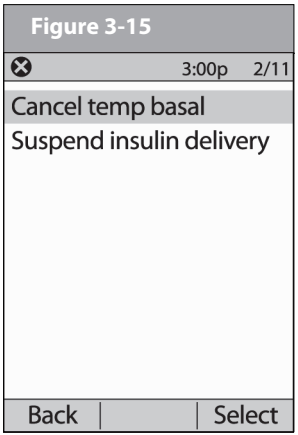
Figure 3-14



Cancel a one-time temporary basal rate

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Suspend/cancel**, then press **Select**.
2. Choose **Cancel temp basal** (Figure 3-15), then press **Select**.
3. Press **Confirm** to cancel the temporary basal shown on the screen.

Figure 3-15



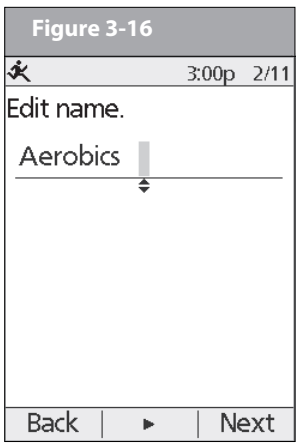
Create a temporary basal preset

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**, then press **Select**.
2. Choose **Presets**, then press **Select**.
3. Choose **Temp basal presets**, then press **Select**.
4. Choose **[add new]**, then press **New**.
5. To use the OmniPod System's default naming system, simply press **Next**. The default naming system automatically assigns program names in numerical order, such as temp basal 1, temp basal 2, temp basal 3.

   Or, to give a different name to the program:

a. Press the **Up/Down Controller** buttons to scroll through the list of characters. An up-and-down arrow symbol on the screen indicates the character you are changing.
b. Press the middle *Soft Key* to move the underscore to the next character.
c. Enter each character one at a time. For example, if you take an aerobics class two nights a week, you might enter A, e, r, o, b, i, c, s (Figure 3-16). (A blank character or space is the first and last option in the scrolling menu.)
d. Press **Next**.

Figure 3-16



NOTE Capitals and lowercase letters are considered the same.

6. For a percent change, choose **Increase** or **Decrease**, then press **Next**.
7. Enter the temporary basal rate (or percent change), then press **Next**.
8. Enter the duration of the temporary basal rate, from 0.5 hours to 12 hours, then press **Next**.
9. Review the temporary basal name, rate or % change, and duration, then press **Save** to accept it.

Enable an existing temporary basal preset

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Temp basal**, then press **Select**.
2. Choose the temporary basal preset you want to use from the list (Figure 3-17 on the next page), then press **Select**.
3. If you want, change the duration for the temporary rate, in half-hour increments, then press **Enter** (Figure 3-18 on the next page).
4. Press **Confirm** to begin the temporary basal rate shown on the screen. The Pod beeps to indicate that the chosen temporary basal preset is running.

Figure 3-17

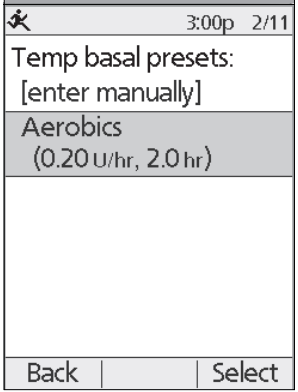
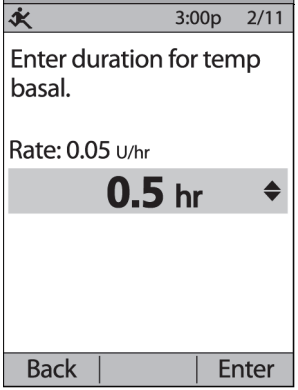


Figure 3-18



Cancel an active temporary basal preset

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Suspend/cancel**;, then press **Select**.
2. Choose **Cancel temp basal**, then press **Select**.
3. Press **Confirm** to cancel the actively running temporary basal preset.

NOTE If you suspend insulin delivery while a temp basal is running, the temp basal will be cancelled when you suspend.

Change, rename, or delete a temporary basal preset

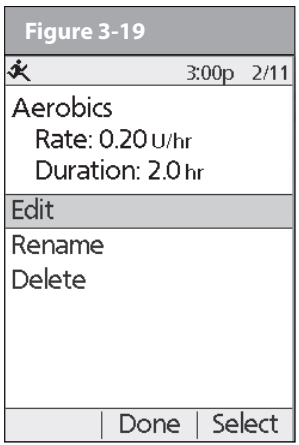
1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**, then press **Select**.
2. Choose **Presets**, then press **Select**.
3. Choose **Temp basal presets**, then press **Select**.
4. Choose a temporary preset from the list, then press **Edit**.

NOTE You cannot edit, change, or delete a temporary basal preset that is actively running.

To change a temporary basal preset

1. Choose **Edit**, then press **Select** (Figure 3-19).

Figure 3-19



2. Enter a new rate (or new percent change), for the preset, then press **Next**.
3. Enter a new duration for the preset, then press **Save**.
4. Press **Done.**

To rename a temporary basal preset

1. Choose **Rename**, then press **Select**.
2. Press the **Up/Down Controller** buttons to enter the characters that spell out the name you want, then press **Save**.
3. Press **Done.**

To delete a temporary basal preset

1. Choose **Delete**, then press **Select**.
2. Press **Delete** to permanently delete the preset. Maximum Basal Rate

n Maximum Basal Rate

What is the maximum basal rate?

The maximum basal rate is a safety feature that limits the basal rate (U/hr) that the Pod can deliver. Once you enter it into the PDM memory, the maximum applies to both regular basal programs and temporary basal rates.

You and your healthcare provider will enter an initial maximum basal rate into your PDM during the setup process (see Chapter 2, Getting Started). You can change it later as you fine-tune your System settings or when your needs change.

Change the maximum basal rate

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**, then press **Select**.
2. Choose **System setup**, then press **Select**.
3. Choose **Bolus/basal/calcs**, then press **Select**.
4. Choose **Max basal**, then press **Select**.
5. Enter a new maximum basal rate, then press **Enter**.

CHAPTER 4

Understanding and Delivering Bolus Doses

What Is a Bolus?

A bolus is an extra dose of *insulin*, delivered when needed to:

- Match the *carbohydrates* (sugar content) in a meal or snack—also known as a meal bolus
- Lower *blood glucose* when it gets too high—also known as a correction bolus

This extra dose is in addition to the *basal rate* delivered throughout the day and night (see Chapter 3, Understanding and Adjusting Basal Rates).

The size of a *bolus dose* depends on the current factors at the time you deliver the bolus:

- Your *blood glucose level*
- Your *insulin-to-carbohydrate ratio*
- Your *correction factor*
- Your target blood glucose
- The amount of *insulin on board (IOB) (active insulin*) from previous meal and correction boluses
- Your *correction threshold I* (correct above threshold), the BG level above which you would like to take insulin to reduce an elevated blood glucose
- Your activity level
- The type and amount of food you eat

With the OmniPod System, it is easy to adapt to any situation. With just a few button presses, you can adjust to unexpected or changing insulin needs.

During setup, you entered bolus dose settings in the PDM (see Chapter 2, Getting Started). You can adjust these settings as you fine-tune your System or when your needs change (see Chapter 6, Using the Personal Diabetes Manager).

Check with your healthcare provider before adjusting these settings.

n Bolus Dose Options

So that you can fully enjoy freedom and flexibility in your life, the OmniPod System offers the following bolus dose options:

Suggested bolus calculator: When you want the System to calculate your *suggested bolus*, based on your personal settings, your current blood glucose, the amount of insulin still active in your body from previous boluses, and the grams of carbohydrate ("carbs" for short) you are about to eat.

Normal bolus: When you need a dose of insulin right away to cover a meal or snack you are about to eat or to reduce a high blood glucose level

Extended bolus: When you are eating high-fat or high-protein foods (which take longer to digest and are slower to affect blood glucose).

When using the extended bolus function the user should check their blood glucose levels more frequently to avoid hypoglycemia or hyperglycemia.

The bolus features in the OmniPod System are designed for flexibility and convenience. You can easily transition from a normal to an extended bolus with just a few button presses.

n Suggested Bolus Calculator

The suggested bolus calculator lets the OmniPod System recommend your bolus based on your personal settings. To review or adjust these settings—including turning the suggested bolus calculator **On** or **Off**—see Chapter 6, Using the Personal Diabetes Manager.

If the suggested bolus calculator is turned **On**, the System automatically calculates a bolus dose. If the suggested bolus calculator is turned **Off**, you must enter a bolus amount manually.

The suggested bolus calculator will display a suggested bolus dose based on the settings you have programmed into the PDM. Check with your healthcare provider before using this feature or adjusting these settings.

If a suggested bolus exceeds the max bolus you have set, the suggested bolus screen displays "Exceeds max bolus." (Figure 4-1 on next page.) If you select **Extend** or **Enter**, the following confirmation is displayed "WARNING: Exceeds max bolus of *nn.nn U*. Accept this bolus and temporarily override your limit?" (Figure 4-2 on next page). Consult your healthcare provider before changing the setting.

Figure 4-1

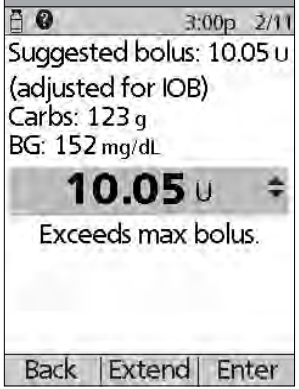
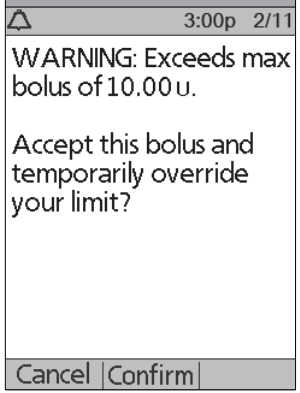


Figure 4-2



How a suggested bolus is calculated

The suggested bolus calculator estimates the suggested amount for each bolus portion based on your personal settings and inputs.

The settings used to calculate a suggested bolus are:

- Target BG
- Insulin-to-carbohydrate (IC) ratio
- Correction factor (CF)
- Duration of insulin action

The factors used to calculate a suggested bolus are:

- current BG
- carbs entered
- insulin on board (IOB)

A suggested bolus can have a correction bolus only, a meal bolus only, or both.

Correction bolus: The correction bolus, as the name suggests, "corrects" for a blood glucose (BG) level above your target BG level.

Meal bolus: The meal bolus provides insulin for the carbohydrates you enter into the System.

Insulin on board (IOB): Insulin on Board (IOB) the amount of insulin still working in your body from previous meal and correction boluses. The amount of time the insulin remains "on board" or "active" depends on what you set for your duration of insulin action.

NOTE The OmniPod System can only subtract insulin on board (IOB) from a suggested bolus when the current BG is known.

For formulas for each element of the suggested bolus calculation, detailed examples, and additional guidelines of how the suggested bolus calculator works, see the Appendix.

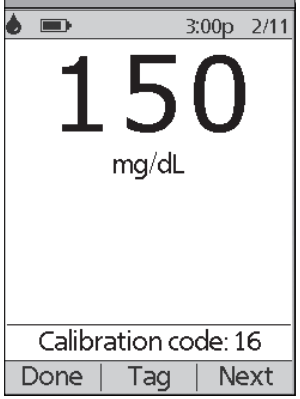
n Deliver a Normal Bolus

Deliver a bolus when suggested bolus calculator is On

1. After you check your blood glucose, the PDM displays the results (Figure 4-3; see the end of Chapter 7, Checking Your Blood Glucose). Press **Next**.

   NOTE A blood glucose value is current for up to 10 minutes after it is tested. So you can wait up to 10 minutes, restart the *bolus* process, and not have to retest your blood glucose in order to include it in the suggested bolus calculator.

Figure 4-3



NOTE When your blood glucose result reads "HIGH" or "LOW," the suggested bolus calculator will be disabled.

NOTE If you use a separate blood glucose meter—not the Personal Diabetes Manager (PDM)—you will need to enter your blood glucose manually. On the **Home** screen, choose **Bolus**, then press **Select**. First, be sure to write down the BG value on a piece of paper. Use the **Up/Down Controller** buttons to enter your current BG value, then press **Yes** if you want this value to be used by the suggested bolus calculator. On the next screen, review the BG value you entered to make sure it is correct, then press **Confirm**.

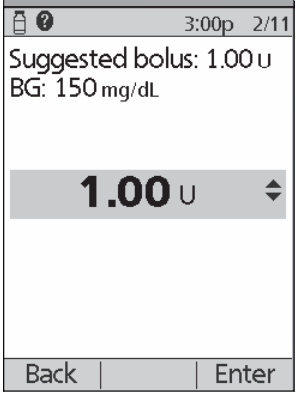
NOTE You can also enter a BG manually by choosing the **More actions** menu, then choosing **Add BG Reading**. See the end of Chapter 7, Checking Your Blood Glucose.

2. If you are not going to eat now, press **No** (Figure 4-4 on the next page). The Suggested Bolus screen appears (Figure 4-5 on the next page). Press **Enter** to accept the suggested bolus.

   Or, if you wish, press the **Up/Down Controller** buttons to increase or decrease the suggested bolus. Then press **Enter** to accept the bolus.

Figure 4-4

Figure 4-5



NOTE In the **Suggested Bolus** screen (Figure 4-5), "adjusted for Insulin on Board (IOB)" appears only when Insulin on Board (IOB) is a factor in the calculation.

TIP To view detailed information about the calculations used for this suggested bolus, press the **User Info/Support** button and scroll through the information screens. Press **Close** to return to the **Suggested Bolus** screen.

3. If you are going to eat now:
   a. Press **Yes** (Figure 4-4), enter the number of carbohydrates you are about to eat, then press **Enter**.
   b. On the next screen, review the BG and carb values to make sure they are correct, and then press **Confirm** (Figure 4-6 on the next page).

      If you've previously entered a carb preset, then either:

      - Use the **Up/Down Controller** buttons to choose **[enter manually]**, then press **Select**. Enter the number of carbohydrates that you are going to eat, then press **Enter**.
      - Use the **Up/Down Controller** buttons to choose favorites, snacks, or meals. From there, select a carb preset you have previously entered (see "Carb Presets" later in this chapter), then press **Select**.

   c. Press **Enter** to accept the suggested bolus (Figure 4-7 on the next page).

      Or press the **User Info/Support** (**?**) button to view calculation information used for this suggested bolus. Press **Close** to return to the **Suggested Bolus** screen, then press **Enter**.

Figure 4-6

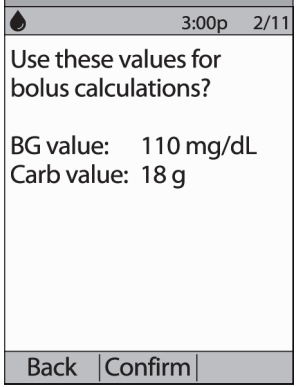
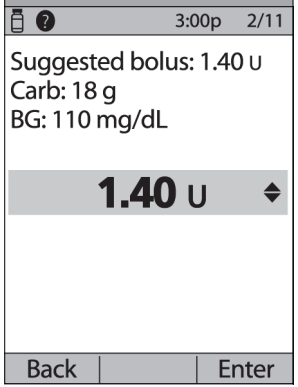


Figure 4-7

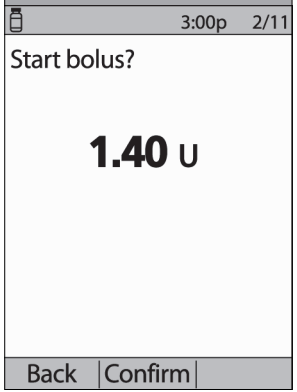


NOTE If the *reverse correction* feature is turned **On** and if your blood glucose level is below your target, the System subtracts a correction amount from the meal portion of the bolus.

NOTE If the reverse correction setting is turned **Off**, the System does not subtract anything for a blood glucose level below your target.

4. If you have set the blood glucose reminder option to **On** and you want to add a reminder:
   a. Press **Yes**.
   b. Enter the time for the reminder, then press **OK**.
5. Press **Confirm** to begin the bolus delivery (Figure 4-8 below).

Figure 4-8



Deliver a bolus manually (suggested bolus calc is Off)

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Bolus**, then press **Select**.
2. Enter the number of units you want to deliver, then press **Enter**.
3. If the blood glucose reminders feature is turned **On**, you can now set a blood glucose reminder.
4. Press **Confirm** to begin the bolus delivery.

NOTE As a safety feature, the OmniPod System only allows you to give a bolus at or below the maximum bolus dose you have set. See Chapter 6, Using the Personal Diabetes Manager, for information on resetting your maximum bolus dose. If suggested bolus calc is **On**, you can enter a temporary manual override to make an adjustment above your max bolus limit (Figure 4-1 and Figure 4-2). Consult your healthcare provider before changing this setting.

n Deliver an Extended Bolus

The extended bolus feature lets the OmniPod System deliver some (or no) insulin now and the remainder over a period of time you choose.

Deliver an extended bolus instead of a normal bolus

1. After you get your suggested bolus, press **Extend** instead of **Enter** (Figure 4-9).

   NOTE If you have set the Extended bolus option to **Off**, the PDM will not display the **Extend** *Soft Key*. For information on turning this feature **On** and **Off** see Chapter 6, Using the Personal Diabetes Manager.

2. Enter the units of insulin or percentage of the bolus that you want to take immediately (Figure 4-10), then press **Enter**.

Figure 4-9

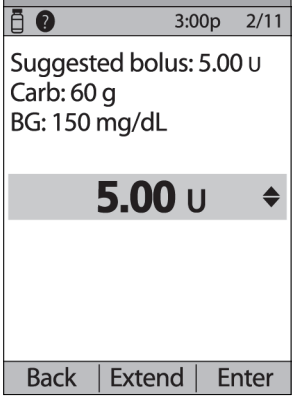
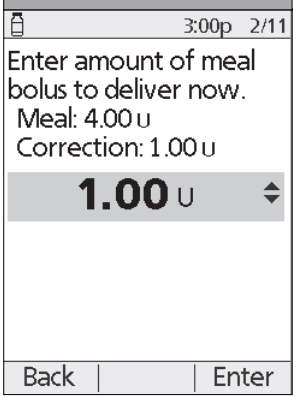


Figure 4-10



NOTE To learn how to set extended boluses in percentages or units, see Chapter 6, Using the Personal Diabetes Manager.

3. Enter the time (up to 8 hours, in 30-minute increments) over which to deliver the remainder of the bolus, then press **Enter** (Figure 4-11 on the next page). In Figure 4-12 (on the next page) you can see a detailed view of the extended bolus.

Figure 4-11

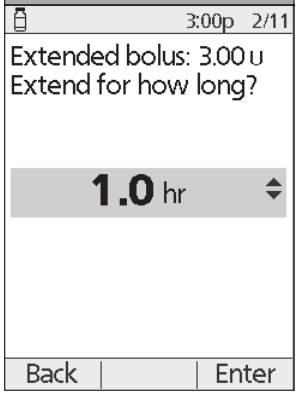
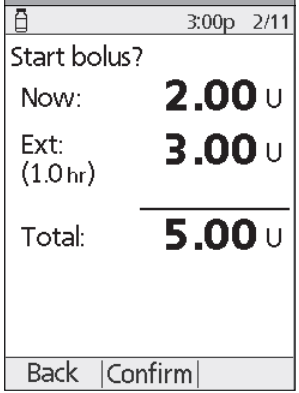


Figure 4-12



4. If the blood glucose reminders feature is turned **On**, you can now set a blood glucose reminder.
5. Press **Confirm** to begin the bolus delivery (Figure 4-12).

NOTE As a safety feature, you cannot deliver two extended boluses at the same time. You can, however, cancel the first extended bolus and replace it with another (see "Replace an Extended Bolus" on page 37). You can deliver a normal bolus while an extended bolus is being delivered.

NOTE As a safety feature, the correction bolus is always delivered first and cannot be extended. Only the meal bolus can be extended. For example:

Total bolus = 5 units
Correction bolus: 1 unit
Meal bolus: 4 units
Deliver now = 2 units
correction bolus: 1 unit
meal bolus: 1 unit
Extend = 3 units
meal portion: 3 units

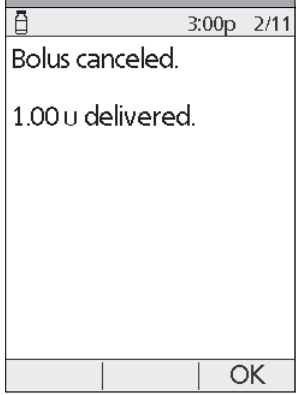
n Cancel Active Boluses

The OmniPod System is extremely flexible, so you can use it to respond to your changing insulin needs. It is easy to cancel an active bolus (one that is currently being delivered), even after insulin delivery has started.

1. To check the Pod status, refer to page 57 for detailed instructions. The **ID** screen must be confirmed before you can check Pod status. An on-screen message appears for as long as a normal bolus is being delivered (Figure 4-13 on the next page).

Figure 4-13

Figure 4-14



NOTE If the bolus has already been completely delivered, the "Delivering bolus" message and **Cancel** do not appear, but the Status screen does appear.

2. Press **Cancel**.

   The Pod beeps to confirm the bolus is cancelled. An on-screen message tells you how much insulin was delivered before you cancelled the bolus (Figure 4-14).

3. Press **OK** to return to the **Status** screen.

NOTE If your suggested bolus contains both a correction bolus and a meal bolus, the correction bolus is always delivered first.

n Replace an Extended Bolus

You can replace one extended bolus with another. The System tells you how much of the first bolus has not yet been delivered.

1. After you see your suggested bolus, press **Extend** instead of **Enter** (see Figure 4-9 on Page 35).
2. Press **Yes** to cancel the active extended bolus (Figure 4-15).

   Or press **Back** to return to the Suggested Meal Bolus screen.

Figure 4-15

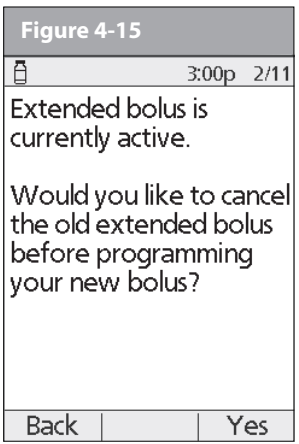
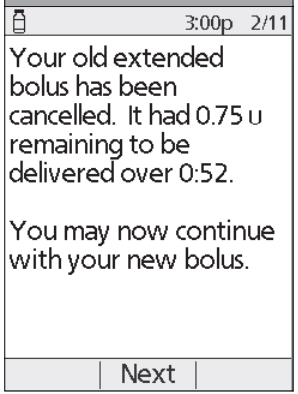

3:00p 2/11
Extended bolus is currently active.
Would you like to cancel the old extended bolus before programming your new bolus?
Back
Yes

Figure 4-16

3. Press **Confirm** (Figure 4-16).
4. The screen displays the amount of the old extended bolus that has yet to be delivered (Figure 4-17 on the next page). Press **Next** to return to the Suggested Meal Bolus screen.

TIP You can add what remained of the old extended bolus to the new one.

Figure 4-17


3:00p 2/11
Your old extended bolus has been cancelled. It had 0.75 u remaining to be delivered over 0:52.
You may now continue with your new bolus.
Next

n Bolus Presets

Bolus presets are bolus amounts that you program for frequent use. For example, if you often take the same bolus at lunchtime, you can create a bolus preset for that amount and name it "Lunch."

NOTE Bolus presets are available only when the suggested bolus calculator feature is turned **Off**. (If the suggested bolus calculator is turned **On**, you can still use carb presets. See "Carb Presets" on Page 40.)

Create a bolus preset

1. On the **Home** screen use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
2. Choose **Presets**, then press **Select**.
3. Choose **Bolus presets**, then press **Select**.
4. Choose **[add new]**, then press **New**.
5. To use the OmniPod System's default naming system, simply press **Next**. The default naming system automatically assigns program names in numerical order, such as bolus 1, bolus 2, bolus 3.

   Or, to give a different name to the program:

   a. Press the **Up/Down Controller** buttons to enter the characters that spell the name you want. An up and down arrow symbol on the screen indicates which character you are changing.

   b. Press the middle *Soft Key* (labeled with the right arrow) to move the underscore to the next character.

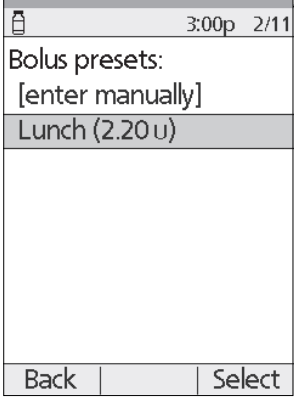
   c. Enter each character one at a time. For example, if you frequently take the same bolus at lunchtime, you might enter L, u, n, c, h (Figure 4-18 on the next page).

d. Press **Next**.

6. Enter the new bolus preset amount, up to the maximum bolus you entered during setup; then press **Next**.

Figure 4-18

Figure 4-19



7. Review the bolus preset name and amount, then press **Save** to accept it.

Enable an existing bolus preset

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Bolus**; then press **Select**.
2. Choose the bolus preset you want to use from the list (Figure 4-19), then press **Select**.
3. Press **Enter** to confirm the bolus preset amount, or, if necessary, use the **Up/Down Controller** buttons to adjust the bolus amount.
4. Press **Confirm** to deliver the bolus shown on the screen.

Change, rename, or delete a bolus preset

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**, then press **Select**.
2. Choose **Presets**, then press **Select**.
3. Choose **Bolus presets**, then press **Select**.
4. Choose a preset from the list, then press **Edit**.

Change a bolus preset

1. Choose **Edit**, then press **Select**.
2. Enter a new insulin amount for the bolus, then press **Save**.

Rename a bolus preset

1. Choose **Rename**, then press **Select**.
2. Press the **Up/Down Controller** buttons to enter the characters that spell out the name you want, then press **Next**.

Delete a bolus preset

1. Choose **Delete,** and then press **Select**.
2. Press **Delete** to permanently delete the preset.

Cancel an active bolus preset

1. Press and hold the **Power** button to turn on the PDM (To check the Pod status, refer to page 57 for detailed instructions. The **ID** screen must be confirmed before you can check Pod status.), if it is not already on. An on-screen message appears as long as a bolus is being delivered.
2. Press **Cancel**.

   The Pod beeps to confirm the bolus is cancelled. An on-screen message tells you how much insulin was delivered before you cancelled the bolus.
3. Press **OK** to return to the **Status** screen.

For more details, see "Cancel Active Boluses" earlier in this chapter.

n Carb Presets

Carb presets are favorite food items, snacks, or meals that you eat frequently. After you enter these items, you can quickly select one when entering carb amounts during the suggested bolus calculator process.

Create a carb preset

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**, then press **Select**.
2. Choose **Presets**, then press **Select**.
3. Choose **Carb presets**, then press **Select**.
4. Choose the category for this carb preset: (**Favorites**, **Snacks**, or **Meals)**, then press **Select**.
5. Choose **[add new]**, then press **New**.
6. To use the OmniPod System's default naming system, simply press **Next**. The default naming system automatically assigns program names in numerical order, such as carb preset 1, carb preset 2, carb preset 3.

   Or, to give a different name to the program:

   a. Press the **Up/Down Controller** buttons to enter the characters that spell the name you want. An up and down arrow symbol on the screen indicates the character you are changing.

   b. Press the middle *Soft Key* (the right arrow) to move the underscore to the next character.

   c. Enter each character one at a time. For example, if you frequently eat a breakfast consisting of plain low-fat yogurt with blueberries, sweetener, and cinnamon, you might enter
   B, l, u, e, [space], Y, o, g, u, r, t (Figure 4-20 on the next page).

   d. Press **Next**.
7. Enter the grams of carbohydrate in the meal, then press **Next**.
8. If you want, enter the grams of fiber, fat, and protein in the meal, and the total calories. Press **Next** after each entry.

NOTE These additional units are not required. If you prefer not to enter them, simply press **Next** repeatedly to skip through the screens.

Figure 4-20

NOTE If you do include grams of fiber in step 8 to the left, the suggested bolus calculator uses carbs minus fiber. Alternatively, in step 7, you can enter the total grams of carbs minus the fiber yourself. Your healthcare provider can best advise you on how to make this entry.

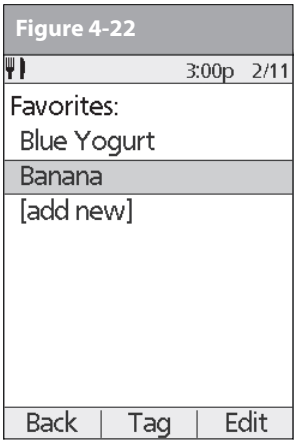
9. Press **Save** to add the preset to the category.

Change or edit a carb preset

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**, then press **Select**.
2. Choose **Presets**, then press **Select**.
3. Choose **Carb presets**, then press **Select**.
4. Choose the category of the preset you want to change, then press **Select** (Figure 4-21).

Figure 4-21

Figure 4-22



To change the category for a carb preset

1. Choose the carb preset you want to move to another category, then press **Tag** (Figure 4-22).
2. Choose a new category, then press **Select**.

To edit a carb preset

1. Choose the carb preset you want to change, then press **Edit**.
2. Press **Edit** again on the next screen.
3. To rename the carb preset, press the **Up/Down Controller** buttons to enter the characters that spell out the name you want, then press **Next**.

   To "erase" characters, press either **Up** or **Down** until you reach the end of the characters, which gives you the option to choose a blank space.
4. Enter the grams of carbohydrate in the meal, then press **Next**.
5. If you want, enter the grams of fiber, fat, and protein in the meal, and the total calories. Press **Next** after each entry.

   NOTE These additional units are not required. If you prefer not to enter them, simply press **Next** repeatedly to skip through the screens.
6. Press **Save** to update the preset.

Delete a carb preset

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**, then press **Select**.
2. Choose **Presets**, then press **Select**.
3. Choose **Carb presets**, then press **Select**.
4. Choose the category of the preset you want to change, then press **Select**.
5. Choose the carb preset you want to delete, then press **Edit**.
6. Press **Delete**.
7. Press **Delete** again to permanently delete the preset.

n Reference Food Library

The Food Library is for reference only. (Food references contained in the library cannot be populated and used for calculations.) Remember to write down values from the food library on a piece of paper to use them in the suggested bolus calculator.

The OmniPod System includes a reference library of over 1,000 common food items. The library shows each item's grams or carbohydrate, fat, protein, and fiber values, and calories for a single portion. You can use this information to determine the carbs for a meal or snack you are going to eat. You can also use it to help you create carb presets for your favorite meals.

The items in the food library are derived from the USDA database, USDA National Nutrient Database for Standard Reference.

Access the reference food library

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **More actions**, then press **Select**.
2. Choose **Food library**, then press **Select.**

The screen displays a list of main food categories (Figure 4-23a and Figure 4-23b).

3. To choose directly from the food categories, choose a main category, then press **Select**. Choose a subcategory, then press **Select**. Choose a food item from the subcategory, then press **View**.

Figure 4-23a

Figure 4-23b

4. To choose from an alphabetical list of foods, press **Index**. Enter the first letter of the food item, then press **Select**. Choose a food item from the alphabetical list, then press **View**.

The screen displays the food item's:

- Name
- Serving size
- Grams of carbohydrate, fiber, fat, and protein
- Total calories

5. Press **OK** to return to the list of main food categories.

CHAPTER 5

Using the Pod

The Pod Change Process

Replace the Pod at least once every 48–72 hours or up to 200 units of insulin (2–3 days). Refer to the insulin labeling and follow your *healthcare provider*'s directions for how often to replace your Pod. If you like, you can set the Personal Diabetes Manager (PDM) to notify you when it is time to replace the Pod (see Chapter 6, Using the Personal Diabetes Manager).

WARNINGS!

- Do NOT apply or use a Pod if the sterile packaging is open or damaged, or if the Pod has been dropped after removal from the package as this may increase the risk of infection. Pods are sterile unless packaging has been opened or damaged.
- Do NOT apply or use a Pod if it is damaged in any way. A damaged Pod may not work properly.
- To minimize the possibility of site infection, do NOT apply a Pod without first using *aseptic technique*. This means to:
  - wash your hands
  - clean the insulin vial with an alcohol prep swab
  - clean the infusion site with soap and water or an alcohol prep swab
  - keep sterile materials away from any possible germs
- Do NOT use a Pod if you are sensitive to or have allergies to acrylic adhesives, or have fragile or easily damaged skin.
- Check often to make sure the Pod and soft *cannula* are securely attached and in place. A loose or dislodged cannula may interrupt *insulin* delivery. Verify there is no wetness or scent of insulin, which may indicate the cannula has dislodged.
- Do NOT apply a new Pod until you have deactivated and removed the old Pod. A Pod that has not been deactivated properly may continue to deliver insulin as programmed, putting you at risk of over infusion and possible hypoglycemia.

- Because insulin Pods use only rapid-acting insulin, users are at increased risk for developing *hyperglycemia* (high *blood glucose*) if insulin delivery is interrupted. If it is untreated, severe hyperglycemia can quickly lead to *diabetic ketoacidosis (DKA)*. DKA can cause symptoms such as breathing difficulties, shock, coma, or death. If insulin delivery is interrupted for any reason, you may need to replace the missing insulin usually with an injection of rapid-acting insulin. Ask your healthcare provider for instructions on handling interrupted insulin delivery.

Gather equipment and supplies

Gather the following before you begin:

- A vial of rapid-acting U-100 insulin (See the warning on page x of the Introduction for a list of insulin's approved for use in the OmniPod System.)

NEVER use insulin that is cloudy; it may be old or inactive. Failure to use rapid-acting U-100 insulin, or using insulin that is expired or inactive, may lead to hyperglycemia or diabetic ketoacidosis (DKA).

- An unopened Pod
- An alcohol prep swab

If you are a first-time OmniPod System user, your healthcare provider will guide you through the steps for initializing and applying your first Pod. Do NOT attempt to apply or use a Pod until you have been trained by your healthcare provider. Use of the System with inadequate training or improper setup could put your health and safety at risk.

Deactivate the current Pod

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **More actions**, then press **Select**.
2. Choose **Change Pod** (Figure 5-1), then press **Select**.
3. Press **Confirm** (Figure 5-2) to deactivate the current Pod.

Figure 5-1

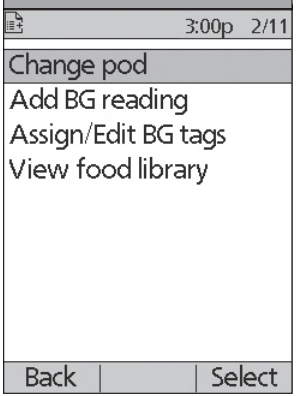


Figure 5-2

4. If an extended bolus or temporary basal or both are actively running, you will see a message similar to that shown in Figure 5-3. Press **Confirm** to accept the cancellation.

   Or press **Back** to return to the **More actions** menu.

Figure 5-3

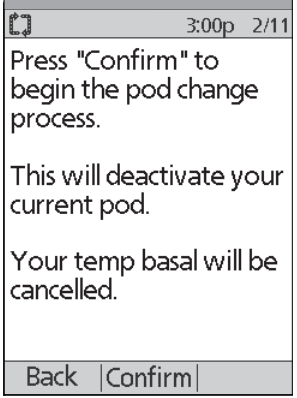

3:00p 2/11
Press "Confirm" to begin the pod change process.
This will deactivate your current pod.
Your temp basal will be cancelled.
Back
Confirm

Figure 5-4

5. After you press **Confirm**, you will see the message in Figure 5-4.

   To remove the old Pod:

   a. Gently lift the edges of the adhesive tape from your skin and remove the entire Pod (Figure 5-5).

Removing the Pod slowly will help to avoid possible skin irritation.

   b. Use soap and water to remove any adhesive that remains on the skin or, if necessary, use an adhesive remover.

   c. Discard the used Pod according to local waste disposal regulations.

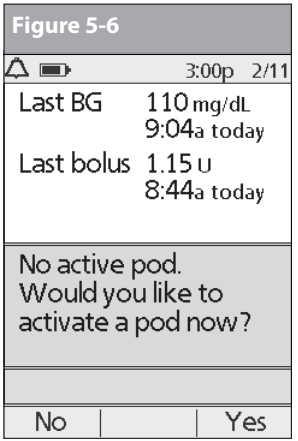
6. After removing the old Pod, press **Next**.

7. Press **Yes** to fill and activate a new Pod (Figure 5-6).

Check the infusion site for signs of infection. See "Avoid Infusion Site Infections" later in this chapter.

Figure 5-5

Figure 5-6



Fill a new Pod

WARNING

Before filling a Pod, ensure that no other Pods are being activated within 24 inches of your PDM.

Before filling a Pod with insulin, ensure that the Pod is above 50° Fahrenheit (10° Celsius). If the Pod has been exposed to temperatures below 50° F (10° C), then allow the Pod to be brought back to room temperature before filling it with insulin.

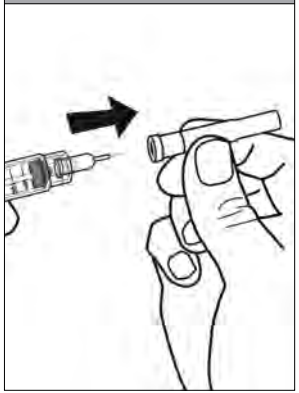
1. Use an alcohol prep swab to clean the top of the insulin vial, then discard the prep swab.
2. Securely twist the fill needle onto the syringe (Figure 5-7).
3. Pull outward to remove the protective cap from the needle (Figure 5-8). Save the cap; you will need it later.

Use care after removing the needle cap and exposing the fill needle.

Only use room temperature insulin when filling the Pod.

Figure 5-7

Figure 5-8



4. Determine the amount of insulin you need to insert into the Pod. For example, if you will use this Pod for 48 hours, you need enough insulin to last you 48 hours. Your healthcare provider will help you determine the correct amount.

NOTE The Pod requires a minimum of 85 units of insulin to begin operation.

NOTE The Pod can deliver up to 200 units of insulin.

5. Draw air into the syringe up to the amount of insulin you want.
6. Insert the needle into the insulin vial and inject the air. This makes it easier to withdraw insulin from the vial.
7. Turn the vial and syringe upside down. Withdraw insulin from the vial into the syringe, expelling any and all air or air bubbles. Fill at least to the MIN (minimum) fill line (Figure 5-9). Refer to the *Care Giver Guide* as an additional reference.

NOTE Any air bubbles present in the fill syringe could be transferred into the reservoir during the fill process. The pod does not purge air that is introduced into the reservoir by way of the fill syringe.

WARNING Failure to expel air bubbles from the fill syringe may result in interrupted insulin delivery.

WARNING Make sure there is no air in the syringe before attempting to fill a Pod with insulin.

8. Remove the needle from the vial and insert it straight down into the insulin fill port on the underside of the Pod (Figure 5-10).

Figure 5-9

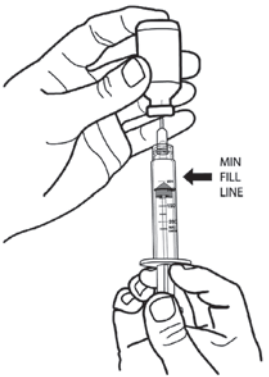
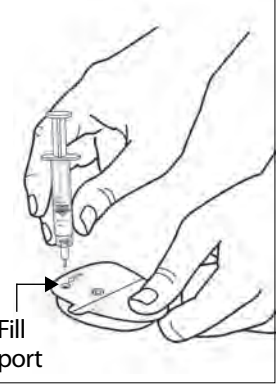


Figure 5-10



⚠ Be sure to only insert the fill syringe into the fill port. Attempting to inject insulin into any other location on the Pod may result in damage to the Pod or loss of insulin.

⚠ To ensure proper fill, do not insert the fill syringe at an angle into the fill port.

⚠ Do not use any other type of needle or filling device besides the syringe provided with each Pod.

9. Depress the syringe plunger to completely empty the insulin into the Pod. The Pod will beep, indicating that the System is ready to proceed to the next step.

WARNING

NEVER use a Pod if you feel resistance when you depress the plunger. This condition can result in interrupted insulin delivery.

10. Remove the needle from the insulin fill port. The port is self-sealing; insulin will not leak after the needle is removed.
11. Place the protective cap back on the needle and remove the needle from the syringe.

Do not insert the fill syringe into the fill port more than once.

WARNING

NEVER inject air into the fill port. Doing so may result in unintended or interrupted insulin delivery.

The fill syringe is intended for single use only and should be used only with the OmniPod System.

12. After you fill the Pod, it will beep twice. After hearing the beeps, **PDM and Pod should be adjacent and touching, either in or out of tray** to ensure proper communication during priming (Figure 5-11 on the next page). Press **Next**.

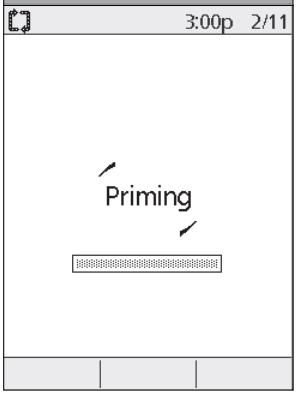
NOTE

As a safety feature, the communication distance between the Pod and PDM is reduced during activation. Once a Pod is primed and communicates with the PDM, the full communication range is restored and the Pod can receive commands only from that PDM.

13. The Pod will only beep if you have filled it with at least 85 units of insulin. If you have filled the Pod with more than 85 units and still do not hear the 2 beeps, please call Customer Care.
14. The System performs a series of safety checks and automatically primes the Pod (Figure 5-12 on the next page). Once complete, the PDM beeps, letting you know that the priming and safety checks were successful.

Figure 5-11

Figure 5-12



NOTE After filling the Pod with insulin, you should complete the Pod change process within 60 minutes. As a reminder that the Pod has been filled, it will beep every 5 minutes to indicate that time is passing. If you do not set up the Pod within 60 minutes, you must deactivate and discard it.

NOTE Once a Pod is activated and communicates with the PDM, it can only receive commands from that PDM, not from any other.

Select the infusion site

Before applying a new Pod, you must first select an appropriate *infusion site*. Due to ease of access and viewing, the abdomen is often used. Your healthcare provider may suggest other potential sites that, like the abdomen, typically have a layer of fatty tissue, such as the hip, back of upper arm, upper thigh, or lower back (Figure 5-13 and Figure 5-14 on the next page).

⚠ Avoid sites where belts, waistbands, or tight clothing may rub against, disturb, or dislodge the Pod. Also avoid sites where the Pod will be affected by folds of skin.

⚠ Change the site each time you apply a new Pod. A new infusion site should be at least 1" away from the last site. (Using the same location repeatedly may reduce insulin absorption.)

⚠ Do NOT apply the Pod within 2" of your navel or over a mole, tattoo, or scar, where insulin absorption may be reduced.

Figure 5-13: Adult

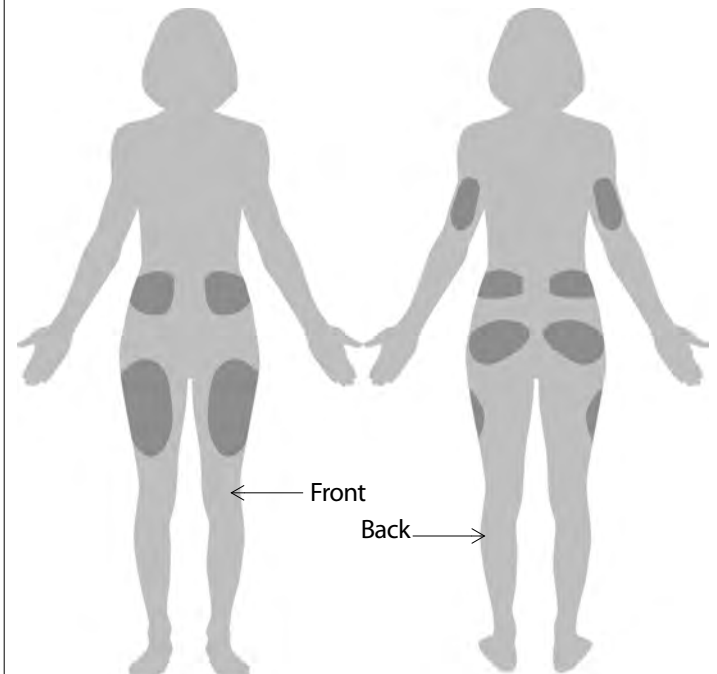
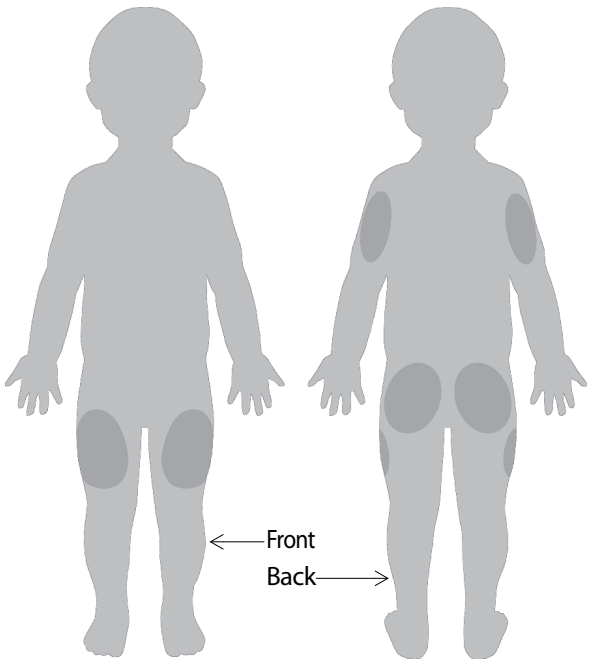


Figure 5-14: Youth



TIP To help avoid condensation from occurring in the viewing window, make sure both your Pod and your insulin are at room temperature.

Prepare the infusion site

You can reduce the risk of infection at the infusion site by following aseptic technique and disinfecting the infusion site. Before applying a new Pod, *always*:

1. Wash hands with soap and water.
2. Use soap to wash the infusion site.

NOTE Antibacterial soap may irritate skin, especially at the infusion site. Ask your healthcare provider how to treat any skin irritation.

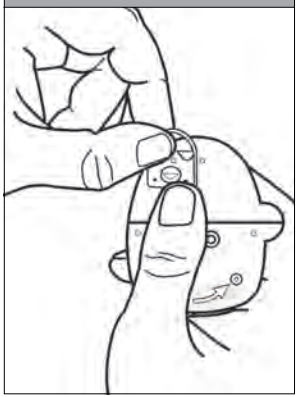
3. Dry the site with a clean towel.
4. Use an alcohol prep swab to disinfect the infusion site. Start at the center of the site and gently rub outward in a circular motion.
5. Let the site air-dry thoroughly. Do not blow on the site to dry it.

Apply the new Pod

Prepare the Pod for applying to your infusion site:

1. To remove the needle cap on the underside of the Pod, place your thumb on the bottom (flat edge) of the needle cap and pull it upwards (Figure 5-15). The needle cap will snap off.

Figure 5-15



2. Verify that the Pod is ready to be applied:
   - Pod is clean and dry.
   - Adhesive pad is intact and undamaged.
   - Pod is intact and in its original condition.

WARNING Verify cannula does not extend beyond adhesive backing once needle cap is removed.

- If Pod is accidentally dropped, discard it; sterility may be compromised.

- If you are unsure the Pod is ready to be applied to the site, press "**Discard**" and do not use it (Figure 5-16 & Figure 5-17). Select a new Pod.

Figure 5-16

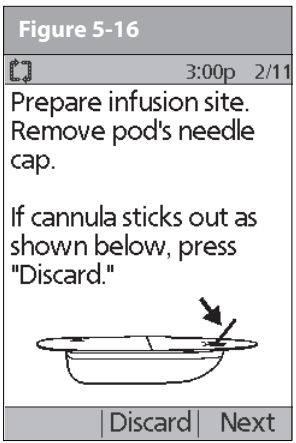


Figure 5-17

NOTE Do not remove the needle cap until you are instructed to do so by the PDM. When you remove the needle cap, a drop of insulin may be visible at the end of the cannula or in the well.

Figure 5-18

3. Using the pull tabs, remove and discard the white paper backing from the adhesive tape (Figure 5-18).
4. Apply the Pod to the prepared infusion site. Press firmly to secure it to your skin.

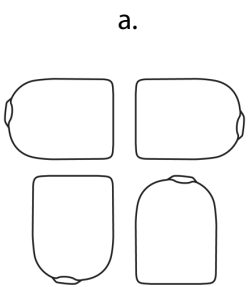
TIP For the Pod to work best, apply it:

a. Crosswise or at a slight angle on your abdomen, hip, upper back, or buttocks (in Figure 5-19 on the next page)

b. Up and down or at a slight angle on your upper arm or thigh (in Figure 5-19 on the next page)

c. At least one inch away from the last site

Figure 5-19



NOTE The Pod's adhesive keeps it securely in place for up to 3 days. However, if necessary, several products are available to enhance adhesion. Ask your healthcare provider about these products. Avoid getting body lotion, creams, or oils near the infusion site; these products may loosen the adhesive.

5. After you securely apply the Pod, press **Next** (Figure 5-15 on page 52 & 5-16 on page 53).

The adhesive is designed for one-time use. Once removed, a Pod cannot be reapplied.

Insert cannula and begin insulin delivery

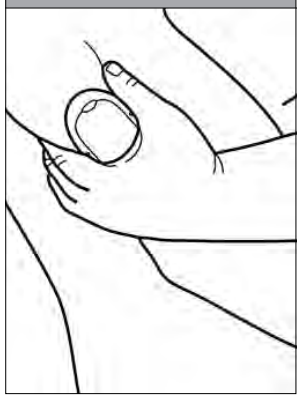
1. To insert the soft cannula, press **Start** (Figure 5-20).

WARNING If you are applying a Pod in a place that does not have a lot of fatty tissue or is very lean, pinch the skin around the Pod (Figure 5-21) after you press **Start** and hold it until the cannula inserts. Occlusions may result in lean areas if you do not use this technique.

NOTE The soft cannula is tinted light blue.

Figure 5-20

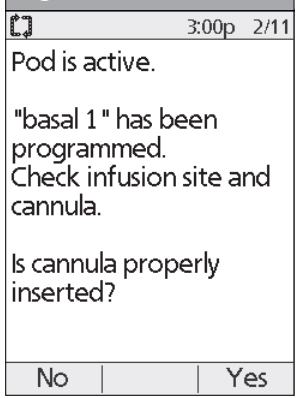
Figure 5-21



The Pod automatically inserts the soft *cannula* below your skin. It takes a few seconds to complete this process. Once the cannula is inserted, the Pod delivers a *prime bolus* to fill the cannula with insulin (Figure 5-22).

Figure 5-22

Figure 5-23



Once the soft cannula is inserted, the PDM indicates that the Pod is active (Figure 5-23).

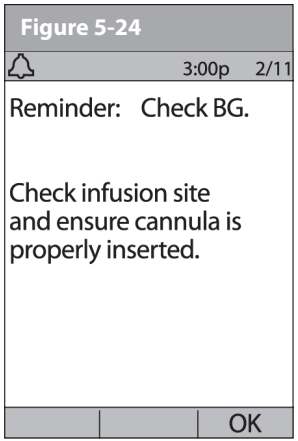
NOTE You will hear a click when the cannula inserts.

WARNING Check the infusion site after insertion to ensure that the cannula was properly inserted. The PDM will automatically remind you to check your blood glucose 1.5 hours after each Pod change (Figure 5-24 on the next page). If the cannula is not properly inserted, hyperglycemia may result. Verify there is no wetness or scent of insulin, which may indicate the cannula has dislodged.

WARNING If you observe blood in the cannula, check your blood glucose more frequently to ensure insulin delivery has not been affected. If you experience unexpected elevated blood glucose levels, change your Pod.

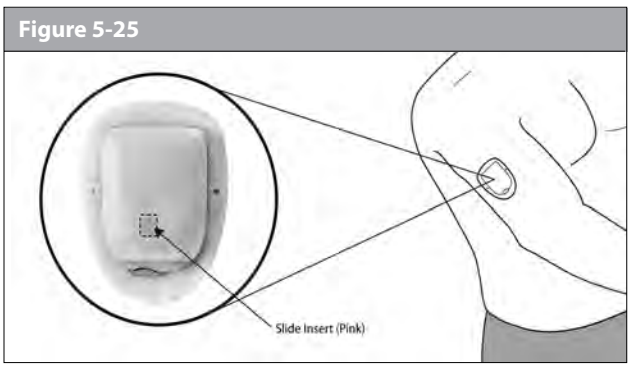
NOTE To help avoid condensation from occurring in the viewing window, make sure both your Pod and your insulin are at room temperature. Condensation may occur in the viewing window, due to perspiration.

Figure 5-24



When you see the pink slide insert in this position, it means that the cannula is inserted (Figure 5-25).

Figure 5-25



2. Press **Yes** if you can see that the cannula is properly inserted. The PDM returns to the **Status** screen.

   Press **No** if you see a problem with the cannula. The PDM instructs you to deactivate the new Pod (Figure 5-26). Press **Discard** to restart the process with a new Pod.

Figure 5-26

NEVER inject insulin (or anything else) into the fill port while the Pod is on your body. Doing so may result in unintended or interrupted insulin delivery.

Check Pod Status

To check Pod status, if the PDM is turned **Off**, press and hold the **Power** button to display the **ID** screen, then press **Confirm** to display the **Status** screen. If the PDM is **On**, press **Back** until you reach the **Status** screen. (If you press and hold the **Power** button, you will turn off the PDM instead.) Or, from the **Home** screen, press **Status**.

The PDM automatically checks the status of the Pod. The PDM then displays the current reservoir volume, PDM battery level, last blood glucose, last bolus dose, active basal program, insulin on board (IOB), and any alarm conditions. See Chapter 6, Using the Personal Diabetes Manager, for details of what you see on the **Status** screen.

NOTE Once a Pod is activated and communicates with the PDM, it can only receive commands from that PDM, not from any other.

If the Pod goes into hazard alarm condition and the PDM is unable to communicate with it to turn off the alarm, you can turn it off manually. See the end of Chapter 10, Alerts and Alarms, for instructions.

Suspend Insulin Delivery

Sometimes you may need to briefly stop insulin delivery (for example, when editing an active basal program or changing the time or date). The OmniPod System lets you suspend all insulin delivery for up to 2 hours. While in suspension, the Pod beeps once every 15 minutes, reminding you that insulin delivery is suspended.

NOTE At any time during a suspension period, press **Resume** to resume the basal program that is programmed for that time.

NOTE Extended boluses and temporary basal rates will be cancelled when you suspend insulin delivery.

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Suspend**; then press **Select**.
2. Enter how long you want to stop all insulin delivery, from 30 minutes to 2 hours, in 30-minute increments (Figure 5-27 on the next page), then press **Enter**.
3. Press **Confirm** to confirm that you want to halt all insulin delivery (basal and bolus). The PDM beeps and an on-screen message lets you know that insulin delivery is indeed suspended (Figure 5-28 on the next page).

   The Pod beeps every 15 minutes until the end of the suspension period. The **Status** screen shows INSULIN SUSPENDED until you resume insulin delivery (see "Resume Insulin Delivery" on page 59).

4. At the end of the suspend time, a Pod *Advisory alarm* occurs (Figure 5-28).

NOTE If a temporary basal or *extended bolus* is in process, the menu item will read **Suspend/cancel** instead, and options for cancelling these programs also appear in the menu. If these options appear, choose **Suspend insulin delivery**.

Figure 5-27

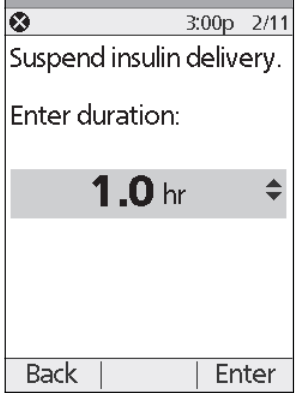


Figure 5-28

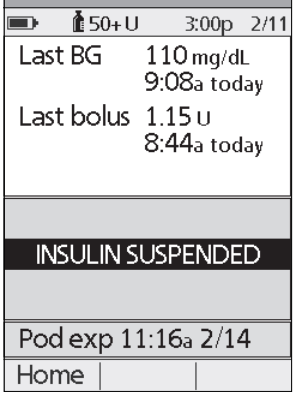
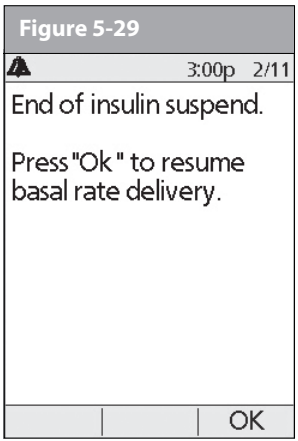


Figure 5-29



5. To resume your programmed basal rate, press **OK** (Figure 5-29).

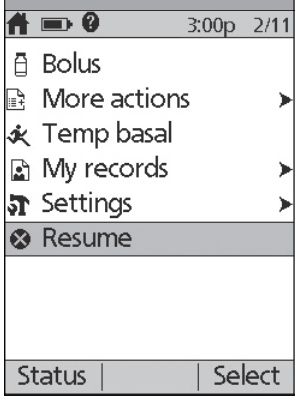
NOTE The Advisory alarm repeats every 15 minutes until you press **OK**.

WARNING Insulin delivery will *not* resume until you press **OK**. If you do not press **OK** to resume insulin delivery, you could develop hyperglycemia (high blood glucose).

Resume Insulin Delivery

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Resume** (Figure 5-30), then press **Select**.

Figure 5-30



2. Press **Confirm** to restart the *basal program* for that time segment.

Avoid Infusion Site Infections

- Always wash your hands and use the *aseptic technique* to prepare the infusion site before applying a Pod.
- Do not apply a Pod to any area of the skin with an active infection. If you are unsure whether to use a specific site, ask your healthcare provider.
- At least once a day, use the Pod's viewing window to check the site for signs of infection and to confirm that the soft cannula is securely in place.
- Be aware of the signs of infection, including pain, swelling, redness, discharge, or heat at the site. If you suspect an infection, immediately remove the Pod and apply a new one in a different location. Then call your healthcare provider.
- Change the Pod as instructed by your healthcare provider.

Get the Most From Your Pod

Avoid extreme temperatures

The Pod's operating temperature is between 40° F and 98.6° F (between 4.4° C and 37° C). Under normal circumstances, your body temperature will keep the Pod well within this range.

Do NOT expose a Pod to direct sunlight for long periods of time. It is recommended that you remove your Pod prior to using hot tubs, whirlpools, or saunas. These conditions could expose the Pod to extreme temperatures and may also affect the insulin inside the Pod.

Remember to check your blood glucose levels frequently before and after removing the Pod. Check with your healthcare provider for guidelines on removing the Pod for extended periods.

Insulin degrades at high temperatures and will freeze near 32° F (0° C). Follow the insulin manufacturer's instructions for use.

Water and your Pod

The Pod is waterproof up to a depth of 25 feet for up to 60 minutes (IPX8). After exposure to water, rinse off the Pod with clean water and gently dry it with a towel.

Do not expose your Pod to water at depths greater than 25 feet or for more than 60 minutes. Check often to make sure the Pod and soft cannula are securely attached and in place. If the cannula is not properly inserted, hyperglycemia may result. Verify there is no wetness or scent of insulin, which may indicate the cannula has dislodged.

The PDM is not waterproof. Do not place it in or near water.

Safe storage

Store unopened Pods in a cool, dry place. Extreme heat or cold can damage Pods and cause them to malfunction. If Pods are exposed to extreme temperatures, allow them to return to room temperature before use.

Pods are sterile unless their packaging is opened or damaged. Do NOT apply or use a Pod if its sterile packaging is opened or damaged, or if the Pod has been dropped after removal from the package as this may increase the risk of infection or serious injury.

CHAPTER 6

Using the Personal Diabetes Manager

The ID Screen

When you first turn on the PDM, it displays the identification (ID) screen (Figure 6-1), which allows you to identify that the PDM is yours. You can personalize the ID screen by adding your name and choosing its color. You must acknowledge the ID screen before you can use the PDM.

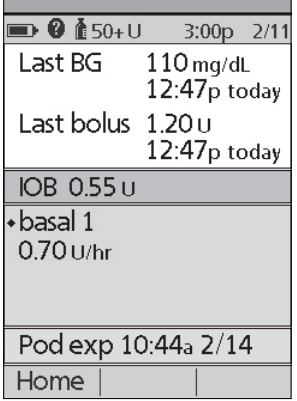
It is important that you always identify the PDM as yours before you use it.

The Status Screen

When a Pod is active and the PDM is turned on, the PDM establishes communication with the Pod to obtain a status check. During the status check, the PDM collects information from the Pod about bolus deliveries, active basal programs, and Pod expiration. The information obtained is then displayed in the status screen, which shows the System's current operating status.

Figure 6-1

Figure 6-2



The **Status** screen (Figure 6-2) displays:

- Current date and time
- Battery life remaining
- Insulin remaining

- Time, date, and result of last blood glucose checked or entered manually
- Time, date, and total amount of last bolus delivered
- Amount of insulin on board (IOB), if suggested bolus calculator is in use
- Name and rate of active basal program or temp basal program
- "Ext bolus," the amount of insulin and the delivery time remaining if an extended bolus is being delivered
- "INSULIN SUSPENDED" if insulin delivery has been suspended
- Time and date when the Pod will expire

NOTE If a Pod has not yet been activated (as in during Pod changes), the screen displays "No active Pod. Would you like to activate a Pod now?" (See Chapter 5, Using the Pod, for details on activating a Pod.)

Insulin gauge and display

One of the important icons on the **Status** screen is the insulin gauge at the top of the screen. It indicates how much insulin is left in the Pod's reservoir. As the reservoir empties, the icon changes to indicate the amount of insulin remaining.

Next to the insulin gauge, the PDM displays the number of units remaining in the Pod. As long as more than 50 units remain, the gauge displays "50+ U." Once the reservoir volume drops to 50 units, the gauge counts down unit by unit. When the volume falls below 5 units, the display changes to "LOW."

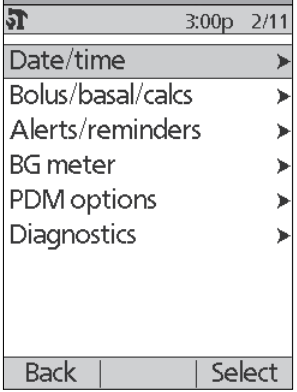
Regularly checking the insulin gauge enables you to plan Pod changes easily. For example, if you know you will need approximately 20 units during your work day and the insulin gauge shows only 17 units remaining, you can either take a new Pod with you or change it before you leave for the day.

PDM settings

You can adjust the PDM settings to meet your individual needs.

1. From the **Status** screen, press **Home**.
2. Use the **Up/Down Controller** buttons to choose **Settings**, then press **Select**.
3. Choose **System setup**, then press **Select**.
4. Choose an option from the **System setup** list, then press **Select** (Figure 6-3 on the next page). Check with your *health-care provider* before making any changes.

Figure 6-3



The System Setup Menu

The **System setup** menu lets you personalize the settings that control the OmniPod System. These include:

- Date and time
- *Bolus doses*, *basal rates*, and bolus calculator settings
- Alerts and reminders
- Blood glucose meter settings and tags
- PDM options
- Diagnostics

You and your healthcare provider entered initial System settings using the Setup Wizard (see Chapter 2, Getting Started). After setup, you can use the **System setup** menu to customize or change those settings, as described in this chapter.

Reset the Date or Time

Occasionally, you need to change date and time settings (for example, to adjust for daylight savings time or after resetting the PDM). As a safety feature, you can change date and time settings only when the Pod is deactivated or when insulin delivery is suspended (see Chapter 5, Using the Pod).

1. Suspend insulin delivery.

   NOTE If you are changing the Pod, you can reset the date or time without suspending by changing the date or time before activating the new Pod.

2. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**; then press **Select**.
3. Choose **System setup**, then press **Select**.
4. Choose **Date/time**, then press **Select**.
5. Choose either **Date** or **Time**, then press **Edit**.

Reset the time

1. To enter the current time, press the **Up/Down Controller** buttons. Press and hold the button to increase or decrease the time faster.
2. Press **12/24 hr** to choose either a 12-hour or 24-hour clock, then press **Enter** (Figure 6-4).

Figure 6-4

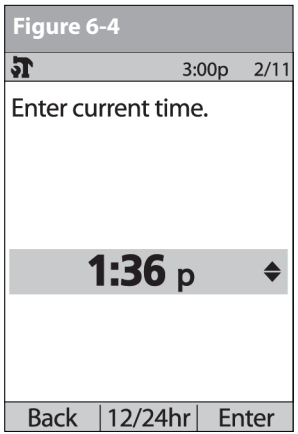
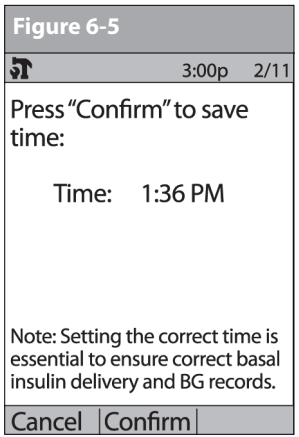


Figure 6-5


3:00p 2/11
Press "Confirm" to save time:
Time: 1:36 PM
Note: Setting the correct time is essential to ensure correct basal insulin delivery and BG records.
Cancel
Confirm

3. Press **Confirm** to accept the new time (Figure 6-5).

NOTE Setting the correct time is essential to ensure correct basal insulin delivery and BG records.

Reset the date

1. Press the **Up/Down Controller** buttons to choose the current year, then press **Next**.
2. Choose the current month, then press **Next**.
3. Choose the current day, then press **Next**.
4. Choose the date format to be displayed by the PDM, then press **Select**.
5. Press **Confirm** to accept the new date and format.

⚠ If you suspended insulin delivery to change the time or date, remember to resume insulin delivery. If you changed the time or date during the Pod change process, remember to activate a new Pod.

n Change Bolus and Basal Settings

You and your healthcare provider entered initial bolus and basal System settings using the Setup Wizard. Using the **System setup** menu, you can edit all the OmniPod System bolus and basal settings as your needs change. Check with your healthcare provider before making any changes.

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**, then press **Select**.
2. Choose **System setup**, then press **Select**.

3. Choose **Bolus/basal/calcs**, then press **Select**.
4. Choose one of the options (Figure 6-6a and Figure 6-6b), then press **Select**. Each option is described below.

Figure 6-6a

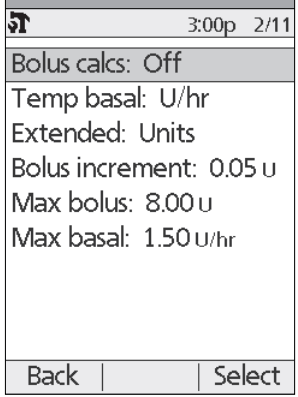
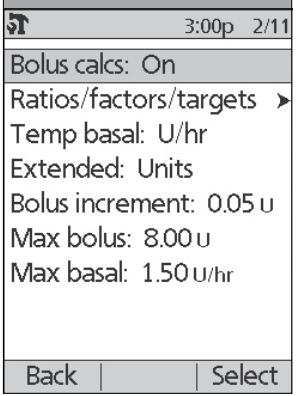


Figure 6-6b

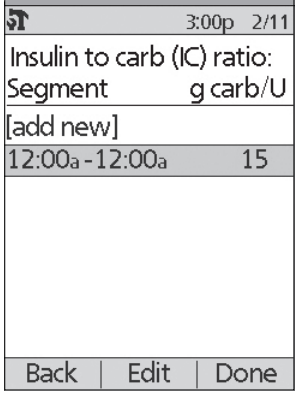


Bolus calcs

When the *suggested bolus calculator* is turned **Off** and you want to turn it **On**, press **On** and follow these steps:

1. **Target BG and correct-above value**—You can edit existing time segments and add segments, up to a total of 8.
   a. To edit an existing *target BG* time segment, choose the segment, then press **Edit**. Use the **Up/Down Controller** buttons to choose a new start time, end time, target BG value, and correct-above value (*correction threshold*). Press **Next** after each entry.
   b. To add a segment, choose **[add new]**, then press **New**. Use the **Up/Down Controller** buttons to choose a start time, end time, target BG value, and correct-above value (correction threshold). Press **Next** after each entry.
   c. When you have completed all the time segments you want, press **Done**, then **Save**.
2. **Min BG for calcs** (minimum blood glucose value allowed for calculating boluses)—Use the **Up/Down Controller** buttons to enter a new minimum BG, then press **Next**.
3. **Insulin-to-carb (IC) ratio**—You can edit existing time segments and add segments, up to a total of 8.
   a. To edit an existing *IC ratio* time segment, choose the segment, then press **Edit** (Figure 6-7 on next page). Use the **Up/Down Controller** buttons to choose a new start time, end time, and IC ratio. Press **Next** after each entry.
   b. To add a segment, choose **[add new]**, then press **New**. Use the **Up/Down Controller** buttons to choose a start time, end time, and IC ratio. Press **Next** after each entry.
   c. When you have completed all time segments, press **Done**, then **Save**.

Figure 6-7



4. **Correction factor**—You can edit existing time segments and add segments, up to a total of 8.
   a. To edit an existing *correction factor* time segment, choose the segment, then press **Edit**. Use the **Up/Down Controller** buttons to choose a new start time, end time, and correction factor. Press **Next** after each entry.
   b. To add a segment, choose **[add new]**, then press **New**. Use the **Up/Down Controller** buttons to choose a start time, end time, and correction factor. Press **Next** after each entry.
   c. When you have completed all time segments, press **Done**, then **Save**.
5. **Reverse correction**—Choose **On** or **Off**, then press **Next**.
6. **Insulin action (duration)**—Use the **Up/Down Controller** buttons to choose a *duration of insulin action*, then press **Done**.
7. Press **OK**.

Ratios/factors/targets

When the suggested bolus calculator is turned **On**, you can view and change all the settings using the **Ratios/factors/targets** menu option. Choose **Review all settings**, then press **Select** (Figure 6-8a) or choose one setting from the menu, then press **Select** (Figure 6-8b). The steps are the same whether you choose all settings or individual ones.

Figure 6-8a

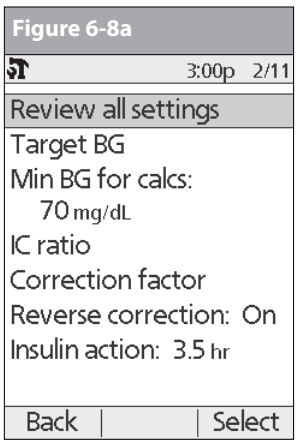
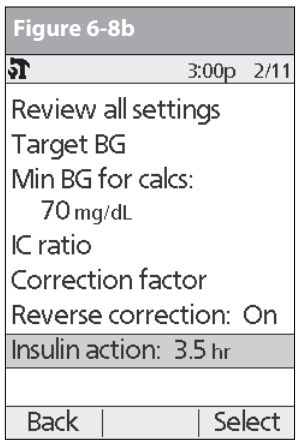


Figure 6-8b



NOTE When the suggested bolus calculator is turned **Off**, the **Ratios/factors/targets** option does not appear in the **Bolus/basal/calcs** menu.

1. **Target BG and correct-above value**—You can edit existing segments and add segments, up to a total of 8.
   a. To edit an existing target BG time segment, choose the segment, then press **Edit**. Use the **Up/Down Controller** buttons to choose a new start time, end time, target BG value, and correct-above value (correction threshold). Press **Next** after each entry.
   b. To add a segment, choose **[add new]**, then press **New**. Use the **Up/Down Controller** buttons to choose a start time, end time, target BG value, and correct-above value (correction threshold). Press **Next** after each entry.
   c. When you have completed all the time segments you want, press **Done**, then **Save**.
2. **Min BG for calcs** (minimum blood glucose value allowed for calculating boluses)—Use the **Up/Down Controller** buttons to enter a new minimum BG, then press **Enter**.
3. **Insulin-to-carb (IC) ratio**—Number of grams of *carbohydrate* covered by one unit of *insulin*. You can edit existing time segments and add segments, up to a total of 8.
   a. To edit an existing IC ratio time segment, choose the segment, then press **Edit**. Use the **Up/Down Controller** butons to choose a new start time, end time, and IC ratio. Press **Next** after each entry.
   b. Review the segment to ensure it is correct, then press **Confirm**.
   c. To add a segment, choose **[add new]**, then press **New**. Use the **Up/Down Controller** buttons to choose a start time, end time, and IC ratio. Press **Next** after each entry.
   d. When you have completed all time segments, press **Done**, then **Save**.
4. **Correction factor**—You can edit existing time segments and add segments, up to a total of 8.
   a. To edit an existing correction factor time segment, choose the segment, then press **Edit**. Use the **Up/Down Controller** buttons to choose a new start time, end time, and correction factor. Press **Next** after each entry.
   b. To add a segment, choose **[add new]**, then press **New**. Use the **Up/Down Controller** buttons to choose a start time, end time, and correction factor. Press **Next** after each entry.
   c. Review the segment to ensure it is correct, then press **Confirm**.
   d. When you have completed all time segments, press **Done**, then **Save**.
5. **Reverse correction**—Choose **On** or **Off**, then press **Select**.
6. **Insulin action (duration) or Insulin on Board (IOB)**—Use the **Up/Down Controller** buttons to choose a duration of insulin action, then press **Enter**.

Temp basal

Choose **%**, **U/hr**, or **Off** to set the mode for temporary basal rates and presets, then press **Select**.

Extended

Choose **%**, **Units**, or **Off** to set the mode for extended boluses, then press **Select**.

Bolus increment

Choose **0.05**, **0.10**, **0.50**, or **1.00** units for bolus increments, then press **Select**.

Max bolus

Use the **Up/Down Controller** buttons to enter the maximum bolus dose you can take, then press **Enter**.

Max basal rate

Use the **Up/Down Controller** buttons to enter the maximum basal rate you can choose, then press **Enter**.

Some settings have preset defaults, but all settings are changeable. See the Appendix for a list of System specifications, including preset default settings.

For additional details on bolus and basal settings, see Chapter 3, Understanding and Adjusting Basal Rates, and Chapter 4, Understanding and Delivering Bolus Doses.

n Alerts and Reminders

In addition to automatic safety alarms (see Chapter 10, Alerts and Alarms), the OmniPod System offers a number of personal settings to help you manage your diabetes. These features are optional. You can turn them on or off at any time, except for the alerts. Those you can set at levels that you find convenient to remind you to change your Pod.

Notifications you can use are:

BG (blood glucose) reminder: Reminds you to check your blood glucose. Choose from **On** or **Off**. The default setting is **Off**. When the reminder is on, the PDM asks you each time you enter a bolus dose whether you want to set a BG reminder, and you can then choose a time interval, in 30-minute increments.

Pod expiration: Reminds you when the Pod is nearing the 72-hour expiration time. Choose a period from 1 to 24 hours before expiration, in 1-hour increments. The default setting is 4 hours. You will hear 2 sets of beeps every minute for 3 minutes. The notification will repeat every 15 minutes until you press **OK** to acknowledge it.

Low reservoir: Alerts you when insulin in the Pod reaches a certain level, so you can plan ahead to change the Pod. Choose a level from 10 to 50 units, in 5-unit increments. The default setting is 10 units.

The Low reservoir alert will escalate to an Empty reservoir hazard alarm when insulin is depleted. Be sure to respond to the alert when it occurs.

Auto-off: Alerts you if the PDM does not receive a Pod status within a predefined period of time. Obtain Pod status by pressing and holding the PDM's **Power** button. Choose a time period from 1 to 24 hours, in 1-hour increments, or choose **Off**. The default setting is **Off**. Refer to page 57 to check Pod status and to **Confirm ID**.

The Auto-off alert will escalate to a hazard alarm if ignored and will result in the deactivation of your active Pod. Be sure to respond to the alert when it occurs.

Turning the PDM on by inserting a blood glucose test strip does *not* send a Pod status to the PDM.

This alert can be especially reassuring if you are prone to hypoglycemia unawareness. Ask your healthcare provider about using this alert and where to set it.

If you use the Auto-off feature, always turn on the PDM with the **Power** button before using the system. This allows the PDM to obtain a Pod status. Refer to page 57 to check Pod status and to **Confirm ID**.

Bolus reminders: Notifies you if you have not delivered a meal bolus, manually or using the suggested bolus calculator, between the times you specify. Choose **On** or **Off** and choose up to 6 time segments.

Program reminders: Pod beeps when a program is in process (see Chapter 3, Understanding and Adjusting Basal Rates; and Chapter 4, Understanding and Delivering Bolus Doses, for details). These include:

- Temporary basal in process
- Extended bolus in process

Choose **On** or **Off**. The default setting is **On**.

Confidence reminders: The Pod or PDM beeps in response to your instructions, so you become familiar with the operation of the OmniPod System and feel confident that you are getting the insulin you need. These notifications include:

- Bolus delivery started
- Bolus delivery completed
- Extended bolus started
- Extended bolus completed
- Temporary basal rate started
- Temporary basal completed

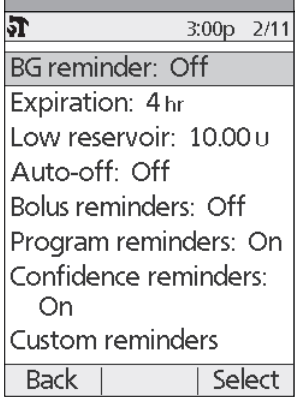
Choose **On** or **Off**. The default setting is **On**.

Custom reminders: Displays text reminders that you enter, at times that you select. You can choose to receive a notification **Daily**, **One time only**, or **Off**. You can change or delete these notifications at any time.

Set alerts and reminders

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**, then press **Select**.
2. Choose **System setup**, then press **Select**.
3. Choose **Alerts/reminders**, then press **Select**.
4. Choose the option you want to set (Figure 6-9), then press **Select**.

Figure 6-9



5. For all except **Bolus reminders** and **Custom reminders**, choose the desired option or set the desired value, then press **Select** or **Enter**.
6. For **Bolus reminders**
   - Use the **Up/Down Controller** buttons to choose **On** or **Off**, then press **Select**.
   - If you chose **On**, you are taken to a new screen where you can add, edit or delete reminders:

   To add a Bolus reminder

   a. Use the **Up/Down Controller** buttons to choose **[add new]**, then press **New**.

   b. Choose a start time, then press **Next**.

   c. Choose an end time, then press **Save**.

   To edit a Bolus reminder

   a. Choose the bolus reminder you wish to edit, then press **Edit**.

   b. Choose **Edit**, then press **Select**.

   c. Enter a new start time, then press **Next**.

   d. Enter a new end time, then press **Save**.

To delete a Bolus reminder

a. Choose the bolus reminder you wish to delete, then press **Edit**.

b. Choose **Delete** then press **Select**.

c. Press **Delete** to remove the bolus reminder.

7. For **Custom reminders**

- Use the **Up/Down Controller** buttons to choose **[add new]**, then press **New**.
- To use the OmniPod System's default naming system, simply press **Next**. The default naming system automatically assigns names in numerical order, such as alert 1, alert 2, alert 3.

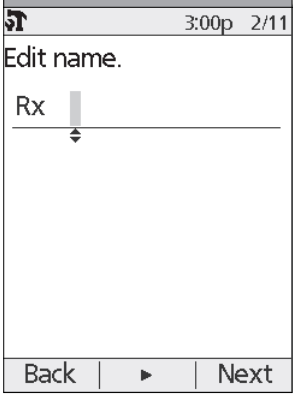
  If you want to give a different name to the reminder:

  a. Use the **Up/Down Controller** buttons to scroll through the list of characters. An up-and-down arrow symbol on the screen indicates the character you are changing.

  b. Press the middle *Soft Key* (the right arrow) to move the underscore to the next character.

  c. Enter each character one at a time. For example, for a reminder to pick up a prescription, you might enter R, x (Figure 6-10). (A blank character or space is the first and last option in the scrolling menu.)

Figure 6-10



  d. Press **Next**.

- Enter the time of day for the reminder, in 30-minute increments, then press **Next**.
- Choose **Daily**, **One time only**, or **Off**, then press **Select**.

NOTE Custom reminders will repeat every 15 minutes until acknowledged.

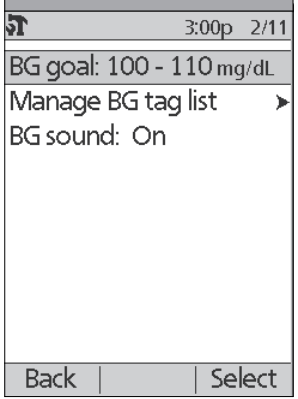
Change Blood Glucose Meter Settings

You can adjust blood glucose (BG) meter settings:

- BG goal lower and upper limits (for BG history)
- Manage BG tags list
- BG sound—**On** or **Off**

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**, then press **Select**.
2. Choose **System setup**, then press **Select**.
3. Choose **BG meter**, then press **Select**.
4. Choose the setting you want to change (Figure 6-11), then press **Select**.

Figure 6-11



Change BG goal limits

To change the **BG goal** limits, press **Edit**, change either or both values, then press **Save**.

Manage the blood glucose tags list

You can create up to 15 custom blood glucose tags and hide any of the standard tags you do not plan to use. Standard BG tags are shown first on the screen (Figure 6-12a), followed by custom tags, and then **[add new]** (Figure 6-12b). For more information about tagging BG readings, see Chapter 7, Checking Your Blood Glucose.

Figure 6-12a

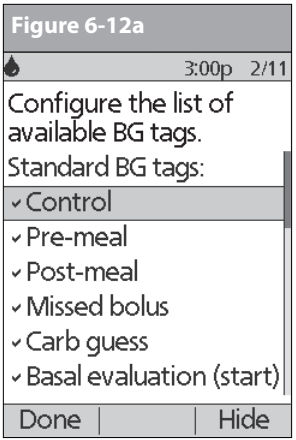


Figure 6-12b

1. To hide or show a standard BG tag, choose the tag, and press **Show** (if it is marked as hidden) or **Hide**.

   Tags you choose to show will be check marked; hidden ones will not be.

2. To add a custom tag, choose **[add new]** at the end of the list of custom tags, then press **New**.

   In the **Edit name** screen, either:

   a. Press **Save** to save the new tag with the default name, **custom tag1**, **custom tag2,** and so on; or

   b. Use the **Up/Down Controller** buttons to choose letters and numbers for a name, followed by the middle *Soft Key* (the right arrow) to move forward one space. Then press **Save**.

3. To delete a custom tag, choose the tag, press **Delete**, then press **Delete** again. Or press **Cancel** to leave the tag unchanged.

Change BG sound

To change **BG sound**, choose **On** or **Off**, then press **Select**.

n Customize the Personal Diabetes Manager

Additional options let you customize how the PDM operates:

ID screen: Identify your PDM by adding your name and choosing a color. The options you set will be shown on the **ID** screen every time you turn on the PDM.

PDM lock: "Locks" the buttons on the PDM. The default setting is **Off**. This safety feature can help avoid accidentally changing basal rates or giving boluses.

Screen time-out: The screen turns off after a time interval that you set, which occurs if you have not pressed any buttons on the PDM. This setting preserves battery power by turning off the screen when you are not using it. Set it at the lowest setting to maximize battery life. The **ID** screen must be confirmed before you can check Pod status.

Press and hold the **Power** button to turn the screen back on. In some cases, if it has been less than 5 minutes since the screen timed out, pressing the **Power** button returns you to the same screen you were using. If it has been longer than 5 minutes, the PDM brings you to the **Status** screen. To check the Pod status, refer to page 57 for detailed instructions.

Backlight time-out: The backlight is on by default while you are using the PDM. The time-out setting dims the backlight and causes the screen to dim when you have not used it within the time interval that you set. Set at the lowest setting to maximize battery life.

TIP For extra brightness on the PDM screen, press and hold the **User Info/Support** button (**?**) for 2 seconds. This enables a "bright mode." The screen will remain in this mode until the PDM times out or you turn it off. To preserve battery life, use this feature only when necessary.

Set PDM options

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**, then press **Select**.
2. Choose **System setup**, then press **Select**.
3. Choose **PDM options** (Figure 6-13), then press **Select**.
4. Choose one of the options (Figure 6-14), then press **Select**.

Set ID screen

To change the ID:

1. Choose **ID**, then press **Select**.
2. Press the **Up/Down Controller** buttons to scroll through the list of characters. An up-and-down arrow symbol on the screen indicates the character you are changing.

Figure 6-13

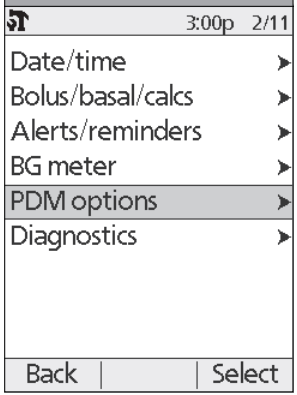


Figure 6-14

3. Press the middle *Soft Key* (labeled with the right arrow) to move the underscore to the next character.
4. Enter each character one at a time. For example, if you want to enter your name, you might enter J, a, n, e, [space], S, m, i, t, h. (A blank character or space is the first and last option in the scrolling menu.)
5. Press **Save**.

As a safety feature, an ID must be entered to enable the PDM to be identified.

To change the ID screen color:

1. Choose **Screen color**, then press **Select**.
2. Use the **Up/Down Controller** buttons to choose a color, then press **Select**.

Set PDM lock

Choose **On** or **Off**, then press **Select**.

If you choose **On**, other PDM options and most other soft keys are locked and will not respond to button presses. To use them, you must first set **PDM lock** to **Off**.

Set the Screen time-out

Choose a time interval, then press **Select**.

When the screen times out and goes black, turn it on again by pressing the **Home/Power** button.

Set the Backlight time-out

Choose a time interval, then press **Select**.

When the screen dims, turn it on again by pressing any button. The PDM will ignore the usual command and re-light the screen.

NOTE The lowest setting will drain the battery the least.

n Set Diagnostic Functions

The **Diagnostics** screen allows you to instantly confirm how the System is working or to completely update settings entered during setup (see Chapter 2, Getting Started). Options include:

Check alarms: Confirms that all alarms work properly when needed. When you select this function, the PDM beeps and vibrates, then the Pod beeps. This function cannot be executed unless insulin delivery is suspended.

WARNING If the PDM fails to beep, immediately call Customer Care. If a Pod is active and fails to beep, change the Pod immediately (see Chapter 5, Using the Pod). Continuing to use the System in these situations may put your health and safety at risk.

Reset PDM (soft reset): Restores all settings in the PDM to the factory defaults.

Resetting the PDM deletes all basal programs, temp basal presets, carb presets, bolus presets, and all suggested bolus settings. Before you use this feature and delete these settings, be sure you have a written record of the information you need. History records will not be deleted.

NOTE As a safety feature, you cannot reset the PDM when a Pod is active. You must first deactivate the Pod.

Diagnostic options

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **Settings**, then press **Select**.
2. Choose **System setup**, then press **Select**.
3. Choose **Diagnostics**, then press **Select**.

To check alarms

1. Choose **Check alarms**, then press **Select**.
2. Press **OK**. The PDM beeps three times and vibrates three times. If a Pod is active, it beeps three times then sounds the alarm tone for 5 seconds.

Be sure to check the alarm function at every Pod change.

To reset the PDM

1. Choose **Reset PDM**, then press **Select**.
2. If the Pod is deactivated, the PDM asks for confirmation and reminds you that you will lose all user settings (Figure 6-15). Press **Confirm** to reset the PDM.

   If the Pod is still active, you will be unable to reset the PDM (Figure 6-16). Press **OK** to return to the **Diagnostics** menu.

Figure 6-15

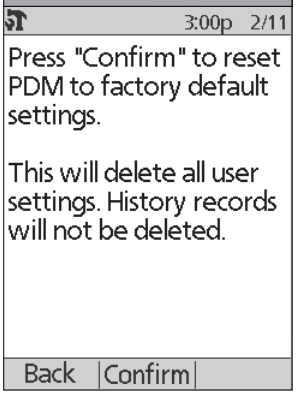

3:00p 2/11
Press "Confirm" to reset PDM to factory default settings.
This will delete all user settings. History records will not be deleted.
Back
Confirm

Figure 6-16

TIP Use the form at the end of this *User Guide* to write down all your settings from the Setup Wizard. If you ever need to reset your PDM, having these settings handy will make setup very easy.

Set a Reminder to Vibrate

For certain reminders, you can choose vibration instead of beeps or vibration followed by beeps, instead of only beeps. If you activate it, the PDM will vibrate for:

- Blood Glucose reminders
- Missed Bolus reminders
- Custom reminders
- "No active Pod" reminders

NOTE The PDM cannot be set to vibrate for hazard or advisory alarms.

To change the type of notification

1. Use the **Up/Down Controller** buttons to choose **Settings**, then press **Select**.
2. Choose **Vibration**, then press **Select**.
3. Choose **Vibrate**, **Vibrate then beep**, or **Off** (beep only), then press **Select**. (**Vibrate then beep** means the PDM will repeat the reminder twice using vibration. After that, it uses beeps.)

   Or press **Back** to return to the **Settings** menu.

Get the Most from Your PDM

Keep it handy

Wireless communication technology means you don't have to keep the PDM right next to the Pod for the Pod to work. Once you set your basal program, the Pod continues to deliver your basal program 24 hours a day, regardless of the location of the PDM. However, you still need the PDM to deliver a bolus, change the basal rate, and so on. You can store the PDM conveniently inside an article of clothing (like a shirt pocket) or put it discreetly into a drawer, briefcase, or purse.

Communicating with the Pod

When you use the PDM to communicate with the Pod, hold the PDM within 5 feet (1.5 meters) of the Pod.

Water and your PDM

Do NOT use IV Prep wipes, alcohol swabs, soap, detergent, or solvents to clean the screen or any other part of the PDM. The PDM is NOT waterproof. Do NOT immerse it or place it in or near water.

Avoid extreme temperatures

Extreme operating temperatures can affect PDM batteries and interfere with System operation. Avoid using the PDM in temperatures below 40°F (4.4°C) or above 104°F (40°C).

Do not store or leave the PDM where it may be exposed to extreme temperatures, such as inside a car. Extreme heat or cold can cause the device to malfunction.

Never attempt to test your blood glucose while your PDM is connected via USB cable to a computer. Doing so could result in electrical shock.

Electrical interference

The PDM is designed to withstand normal radio interference and electromagnetic fields. However, as with all wireless communication technology, certain operating conditions can interrupt communication. For example, electric appliances such as microwave ovens and electric machinery located in manufacturing environments may cause interference. In most cases, interruptions are easy to resolve (see Chapter 11, Communication Failures).

Only connect a USB cable to your PDM when downloading data to a computer. Other PDM functions are disabled while a USB cable is connected, and the PDM cannot communicate with the Pod.

When you connect a USB cable to the PDM, only use a cable that is less than or equal to 9 feet (2.7 meters) in length.

CHAPTER 7

Checking Your Blood Glucose

n The Built-in FreeStyle® Blood Glucose Meter

With the FreeStyle® *blood glucose meter*, checking your blood glucose requires a very small sample size, 0.3 microliters of blood. Refer to your FreeStyle test strip instructions for use for important test strip information. You may want to test for low blood glucose:

- When you feel symptoms such as weakness, sweating, nervousness, headache, or confusion
- When you have delayed a meal after taking *insulin*
- When your healthcare provider advises you to do so

Keep the system and the FreeStyle® accessories away from young children, as they contain small parts that may be dangerous if swallowed.

Only use FreeStyle® test strips and FreeStyle® control solution with the System. Using other brands of test strips and control solutions with the System can produce inaccurate results.

Never attempt to test your blood glucose while your PDM is connected via USB cable to a computer. Doing so could result in electrical shock.

This Device is intended for self-testing by the user.

Please read all the instructions provided in this *User Guide* and practice the testing procedures before using the system and FreeStyle® accessories. Follow the guidance of a healthcare professional for proper blood *glucose* monitoring.

The FreeStyle® Blood Glucose Test Strips

Complete information on the FreeStyle® test strips (such as interferences and performance) can be found in the test strip package insert. Please read all instructions provided on the test strip package insert before using the OmniPod System and FreeStyle accessories.

Important test strip information

- Store the blood glucose test strip package in a cool, dry place between 40° and 86° F (4.4° and 30° C).
- Use test strips only when the PDM is within its operating temperature range, between 40° and 104° F (4.4° and 40° C).
- Keep test strips away from direct sunlight and heat.
- Store test strips in their original vial only; never transfer them to another vial or any other container.
- Never store individual test strips outside the vial.
- After removing a blood glucose test strip from the vial, immediately close the vial cap tightly.
- With clean, dry hands, you can gently touch the test strip anywhere when removing it from the vial or inserting it into the test strip port.
- Do not bend, cut, or alter blood glucose tests strips in any way.

WARNING Do not use strips beyond the expiration date printed on the package, as this may cause inaccurate results.

NOTE For detailed storage and usage information, refer to the package insert in the box containing the test strip vial.

WARNING The cap or vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

The FreeStyle® Control Solution

The FreeStyle® control solution (Figure 7-1) is a red liquid that contains a fixed amount of glucose and has two important uses:

- To ensure that your meter and test strips are working together properly
- To practice testing without having to use your own blood

Three levels of control solution are available: Low, Normal, and High. For information on how to obtain control solution, call Insulet's Customer Care (24 hours/7 days): 800-591-3455. When calling from outside the United States: 781-457-5098.

Figure 7-1

When to perform a control solution test

You should perform a control solution test:

- When you suspect that your meter or test strips are not working properly
- When you think your test results are not accurate or if your test results are not consistent with how you feel
- When you drop or damage your PDM or expose it to liquids
- When your healthcare provider advises you to do so

Check that the meter and test strips are working

A control solution test follows the same procedure as a blood glucose reading, except that you use a sample of control solution instead of a drop of blood. (See "Performing a Blood Glucose Reading" later in this chapter.)

When you perform a control solution test, if the reading is within the control solution acceptable range, the meter is working properly.

Control solution expiration date

FreeStyle® control solution is good for 3 months after opening the bottle, or until the expiration date printed on the label, whichever comes first. Count forward 3 months from the date you open a new bottle of control solution. This is your discard date. Write this date on the side of the control solution bottle. For example, if you open the control solution on January 15, count forward 3 months to April 15. This is the discard date to record on the bottle, as well as the date to discard it and begin using a new bottle.

Ensure accurate control solution results

- Replace the cap on the control solution bottle immediately after using it.

Use only FreeStyle® control solution with the System. Other brands of control solution may produce inaccurate results with this System.

Do not use control solution past the expiration date or you may get inaccurate results.

- Do not add water or any liquid to control solution.
- Control solution tests are specified to be accurate only when performed between 59° and 104° F (15° and 40° C).

Results from FreeStyle® control solution tests do not reflect your *blood glucose level*.

- The control solution test results should fall within the range printed on the test strip vial label.

The control solution range is a target range for control solution only. It is not a target range for your blood glucose.

If control solution results are out of this range, REPEAT THE TEST.

Out-of-range control solution results

Out-of-range test results may be caused by:

- Expired or bad control solution
- Expired or bad test strip
- Error in performing test
- Code on test strip vial does not match code set in the PDM
- Malfunction of the System
- Control solution test done outside 59° to 104° F (15° to 40° C)

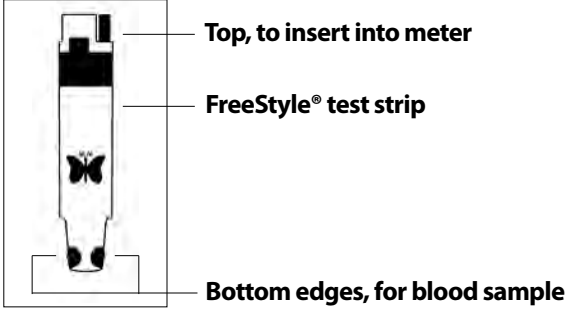
If your control solution test results continue to fall outside the range printed on the test strip vial:

1. The System may not be working properly.
2. Do not use the System to test your blood glucose.
3. Call Insulet's Customer Care (24 hours/7 days): 800-591-3455. When calling from outside the United States: 781-457-5098.

n Performing a Control Solution Test

1. Turn the PDM On, using the Home/Power button.
2. Grasp the bottom of the test strip with the printed side facing up (Figure 7-2).

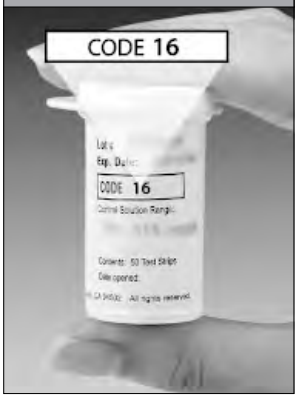
Figure 7-2



3. Insert the top of the test strip into the test strip port (Figure 7-3 on the next page) until it stops. This turns on the PDM and displays the code number on the screen. Refer to page 57 to check Pod status and to **Confirm ID**.

Figure 7-3

Figure 7-4



WARNING

Always verify and be prepared to adjust the code on the PDM to match the code number on the test strip vial (Figure 7-4). The code number on the screen must match the code number on the side of your test strip vial. They must always match or your results will be inaccurate. (See "Set the blood glucose test strip code" later in this chapter.)

NOTE

If you need to adjust the code number after the PDM has moved to the next screen, just press the **Up/Down Controller** buttons. The code screen reappears and you can adjust the number. The code number remains on the PDM screen for your reference until you have completed the control test.

NOTE

From some PDM screens, you cannot access the Freestyle® blood glucose meter. For example, you cannot use the meter while you are activating a Pod or when an alert, alarm or communication error screen is displayed. In these cases, if you insert a test strip, the PDM beeps to alert you.

4. To help you see the test strip port in reduced lighting, when you insert a test strip into the PDM, you can turn on the port light. Press the middle *Soft Key* labeled **Light**. To turn the light off, press **Light** again.
5. Wait for the PDM to display "Apply a blood sample to the strip" on the screen (Figure 7-5).

Figure 7-5

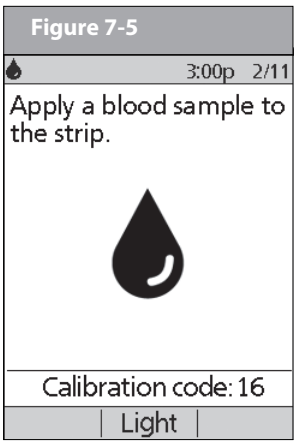
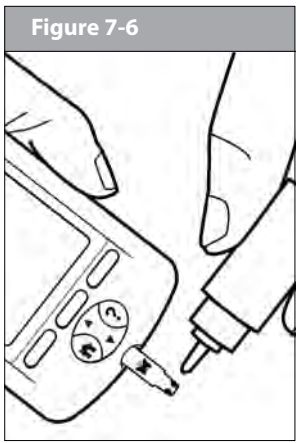


Figure 7-6



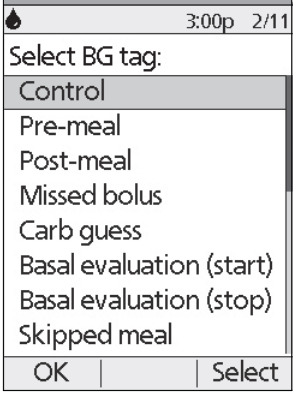
6. Gently touch only ONE EDGE of the test strip to the control solution. Specifically, apply the control solution to the test strip edge next to one of the dark-colored half-circles (Figure 7-6 on the previous page). If **BG sound** is set to **On**, the PDM beeps when the test strip is full.

   If you do not apply the sample within 10 seconds, the strip port light turns off. To turn it on again, press **Light**.

   The "Checking" screen appears while the sample is processing (Figure 7-7). The strip port light turns off when the sample is accepted.

Figure 7-7

Figure 7-8



NOTE Do not apply control solution to both edges of the test strip.

   If **BG sound** is set to **On**, the PDM beeps twice. The result appears on the screen.

7. To mark the result as a control solution result rather than a blood glucose test:
   a. Press **Tag**.
   b. Use the **Up/Down Controller** buttons to select **Control** (Figure 7-8), then press **Select**. You can select a second tag for the test result in the same way.

      NOTE You can select a maximum of 2 tags.

   c. Press **OK**.
8. If you do not want to mark the test as a control solution test, press **Next** instead of **Tag**.

NOTE If the *suggested bolus calculator* feature is turned **Off**, the **Bolus** soft key appears instead of **Next**.

NOTE If you mark a test as a control solution test by mistake, you can unmark it: Press **Tag**, select **Control**, then press **Clear**.

9. Compare the control solution test result to the range printed on the test strip vial label. If the result does not fall within the range, repeat the test. If the result still does not fall within the range, call Insulet's Customer Care (24 hours/7 days): 800-591-3455. When calling from outside the United States: 781-457-5098.
10. Remove the test strip. If the strip port light was turned on, it now turns off.

    If you remove the test strip before this step, you will still see the available soft keys.

NOTE Be sure to discard used test strips. (You can only use test strips once.) Used test strips are considered bio-hazardous material.

n Performing a Blood Glucose Reading

Figure 7-9 shows the parts of the lancing device.

WARNING To ensure accurate results, wash your hands and the test site (for example, your upper arm) with soap and water. Do not leave any cream or lotion on the test site. Thoroughly dry your hands and the test site.

Lancing device depicted in Figure 7-9 is representative only. Please follow the instructions included with your specific lancing device.

Figure 7-9

Cocking handle
Depth settings dial
Depth indicator window
Release button
Clear cap, for testing sites other than the finger
Gray cap, for testing on the fingers

Prepare the lancing device

1. Snap off the cap on the lancing device at an angle (Figure 7-10).

Figure 7-10

Figure 7-11

2. Insert a new lancet firmly into the white lancet holder cup (Figure 7-11). Pushing the device into the cup may cock the device, which is fine.
3. Hold the lancet firmly in place with one hand. With your other hand, twist off the rounded top (Figure 7-12).

Figure 7-12

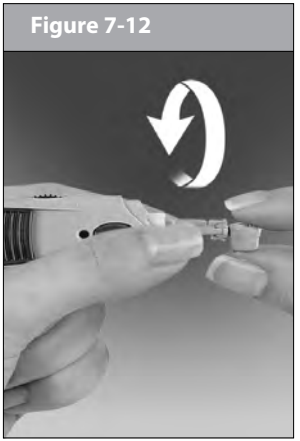


Figure 7-13

4. Replace the cap until it snaps or clicks into place (Figure 7-13). Be careful not to touch the exposed needle on the lancet.

NOTE Consult your lancing device instructions to ensure proper usage.

Lancing device depicted in Figures 7-10, 7-11, 7-12 and 7-13 is representative only. Please follow the instructions included with your specific lancing device.

Figure 7-14

Figure 7-15

5. Pull out the cocking handle until it clicks (Figure 7-15). (You may have already cocked the handle in step 2. This is okay.)

You are now ready to perform a blood glucose test.

Insert the blood glucose test strip

1. Insert a new blood glucose test strip into the test strip port until it stops. The test strip port is at the bottom of the PDM.

Lancing device depicted in Figures 7-14 and 7-15 is representative only. Please follow the instructions included with your specific lancing device.

NOTE

From some PDM screens, you cannot access the FreeStyle® blood glucose meter. For example, you cannot use the meter while you are activating a Pod or when an alert, alarm or communication error screen is displayed. In these cases, if you insert a test strip, the PDM beeps to alert you.

2. To help you see the test strip port in reduced lighting, press the middle soft key labeled **Light**. To turn the light off, press **Light** again.
3. Insert only the top end of the strip into the test strip port (Figure 7-16 and Figure 7-17).

Figure 7-16

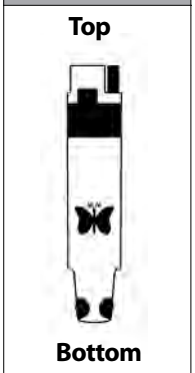
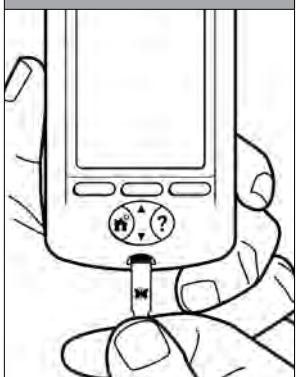


Figure 7-17



NOTE If you do not start the test within 2 minutes, the PDM powers off. To restart the PDM, take out the unused strip and reinsert it, or simply press and hold the **Power** button to turn on the PDM. Refer to page 57 to check Pod status and to **Confirm ID**.

Set the blood glucose test strip code

After you insert the strip, the PDM displays a code number (Figure 7-18). This number must match the code on the side of the vial.

Figure 7-18

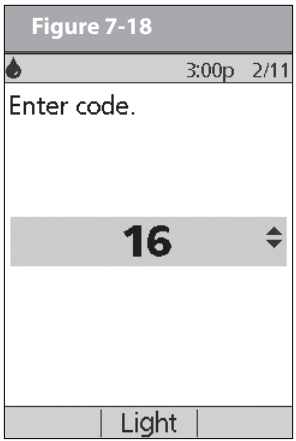
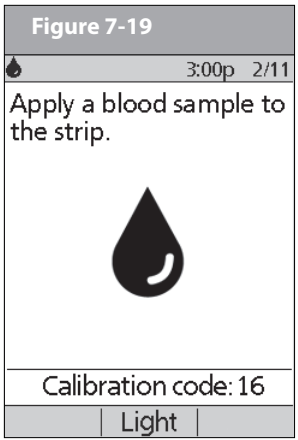


Figure 7-19



To change the code number, press the **Up/Down Controller** buttons until the number matches the number on your vial. The numbers are between 1 and 50.

If you do not adjust the code number within 2 seconds, the next screen appears automatically (Figure 7-19).

NOTE If you need to adjust the code number after the PDM has moved to the next screen, just press the **Up/Down Controller** buttons. The code screen reappears and you can adjust the number. The code number remains on the PDM screen for your reference until you have completed the BG test.

WARNING The code number on the screen must match the code number on the side of your test strip vial (Figure 7-4). They must always match or your results will be inaccurate.

1. To stimulate blood flow, keep your hand warm or lower your hand to waist level and gently massage your finger.

2. Set the depth setting on the lancing device (Figure 7-20).

Figure 7-20

Figure 7-21

3. Lightly touch the lancing device (with the cap) against the side of your fingertip (Figure 7-21).
4. Press the release button.
5. Gently squeeze your finger, if needed, until a blood drop the size of a pinhead forms.

Lance your upper arm or hand

1. To bring fresh blood to the surface of the test site, rub the site vigorously for a few seconds until you feel it getting warm.

Figure 7-22

Figure 7-23

2. Set the depth setting on the lancing device (Figure 7-22).
3. Hold the lancing device (with the clear cap) against the top of your test site.
4. Press the release button. Do not lift up; continue to hold the button and gradually increase pressure against the site for several seconds (Figure 7-23).
5. While holding the lancing device on your test site, look through the clear cap. The blood sample should be about the size of a pinhead.

Lancing device depicted in Figures 7-20, 7-21, 7-22 and 7-23 is representative only. Please follow the instructions included with your specific lancing device.

6. Lift the lancing device straight up; be careful not to smear the blood sample on your test site.

WARNING

Measurements obtained from alternate site testing should not be used to calculate insulin doses with the OmniPod System.

Avoid lancing areas with obvious veins or moles to avoid excess bleeding. Also avoid lancing areas where tendons or bones stick out (for example, hand bones).

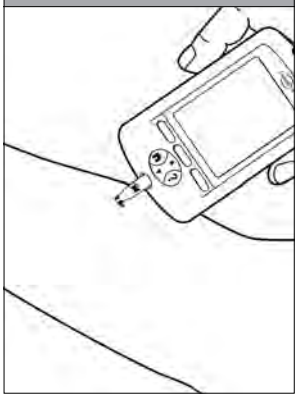
7. If you see any signs of deterioration of the PDM (i.e. cracking separation, discolorations.) Please contact customer care.

Fill the blood glucose test strip with blood

1. Turn the PDM On, using the Home/Power button.
2. Make sure that the strip is in the PDM and the PDM is powered on. If the PDM has powered off, take out the strip and reinsert it (Figure 7-24), or simply press and hold the **Power** button to turn on the PDM. Refer to page 57 to check Pod status and to **Confirm ID**.

Figure 7-24

Figure 7-25



3. Bring the strip to the blood sample at a slight angle (Figure 7-25).

   If you do not apply the sample within 10 seconds, the strip port light turns off. To turn it on again, press **Light**.

   Use only one edge of the blood glucose test strip per test. Do not apply blood to both edges (Figure 7-26 on the next page). Only use strips once. Discard used strips.

   The test strip pulls the blood into the strip through the edge (Figure 7-27 on the next page).

Figure 7-26

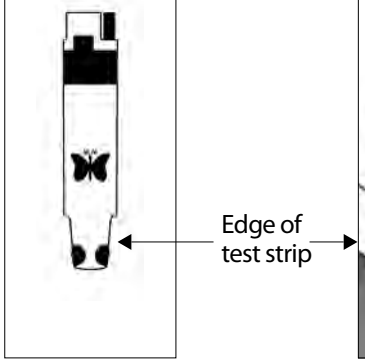
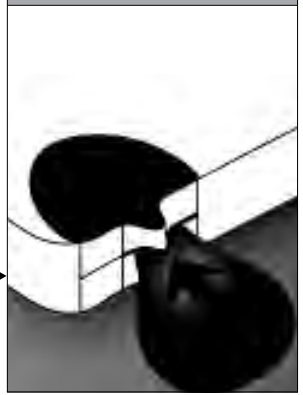


Figure 7-27



WARNING

The lancing device is intended for individual use and should not be shared. If the device is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be decontaminated prior to use by the second person (see Appendix A).

Do not:

- Press the strip against the test site
- Scrape the blood onto the strip
- Apply blood to the flat side of the strip
- Apply blood to the strip when it is out of the meter
- Put blood or foreign objects into the test strip port

1. Do not pull the test strip away from the sample until you hear 1 beep or see the word "Checking" on the screen (Figure 7-28). This means you applied enough blood and the meter is reading your glucose.

Figure 7-28

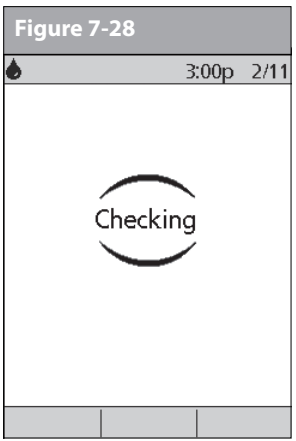
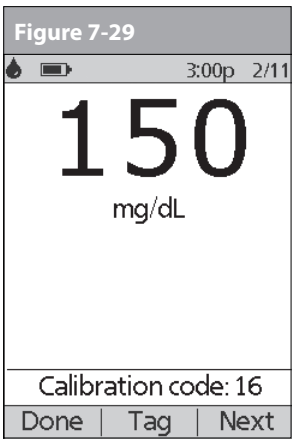


Figure 7-29



2. If after 5 seconds the PDM does not display "Checking," the sample may be too small. If needed, add more blood to the same edge of the strip for up to 60 seconds from the time of the first application.

   The strip port light turns off when the blood sample is accepted. The reading is complete when you hear 2 beeps (if **BG sound** is turned **On**) and the PDM shows your reading on the screen (Figure 7-29 on the previous page).

   The time the test takes depends on your blood glucose level. The higher your glucose level, the longer it takes to get a result.

3. To mark the result as a pre- or post-meal test, to indicate a level of exercise or to indicate other situations connected to this *blood glucose reading*, press **Tag**. Then:

   a. Use the **Up/Down Controller** buttons to select a tag, then press **Select** (Figure 7-30). You can select a second tag for the reading in the same way.

      To learn how to manage your list of tags and to add custom tags, see "Manage the blood glucose tags list" in Chapter 6, Using the Personal Diabetes Manager.

   b. Press **OK** to return to the reading screen (Figure 7-30), then press **Next**.

4. If you do not want to mark the test, press **Next** instead of **Tag**.

NOTE If the suggested bolus calculator feature is turned **Off**, the **Bolus** soft key appears instead of **Next**.

5. Remove the test strip. If the strip-port light was turned on, it now turns off.

Figure 7-30

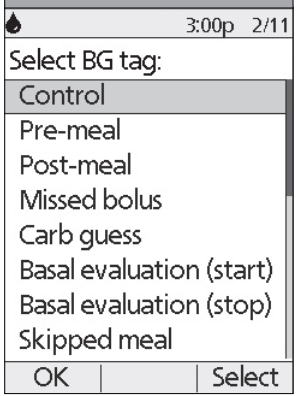


Figure 7-31

Remove the lancet

When you have finished testing, remove the lancet from the lancing device (Figure 7-31). Discard the used lancet properly in a puncture-resistant container. Then wash your hands with soap and water.

NOTE See "Cleaning and disinfecting" in the Appendix for instructions on how to clean or disinfect your PDM.

Lancing device depicted in Figures 7-31 is representative only. Please follow the instructions included with your specific lancing device.

Blood Glucose Results and the Suggested Bolus Calculator

If the suggested bolus calculator feature is turned **On** when you check your blood glucose, the PDM will display the result. From here, press **Next** to enter carbs (if eating) and have the System calculate a suggested bolus. (See "Suggested Bolus Calculator" in Chapter 4, Understanding and Delivering Bolus Doses.)

NOTE If you use the suggested bolus calculator within 10 minutes after taking a blood glucose reading, or if you store a BG reading (for example, one you enter manually) within the same 10 minutes, that BG value will be used automatically in the suggested bolus calculator process (Figure 7-32).

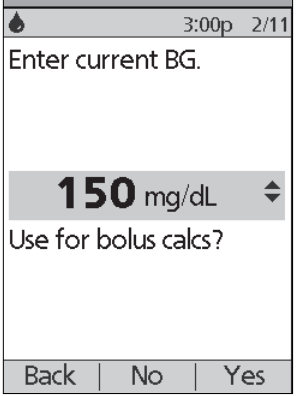
If the suggested bolus calculator feature is turned **Off**, the **Next** soft key does not appear. Instead:

Press **Bolus** to open a screen where you can enter a bolus manually.

Or press **Done** to return to the **Status** screen to see the most recent BG result.

The BG result, either from the PDM or from manual entry, is stored in the System's history, whether suggested bolus calculator is turned **On** or **Off**. (See "Blood Glucose Records" in Chapter 8, Understanding Your Records.)

Figure 7-32



NOTE The **Bolus Entry** screen does not open if:

- A regular bolus is currently in process
- The meter temperature is out of range
- You have tagged this BG reading as a **Control**
- The BG reading is less than your "Min BG for calcs"
- Insulin is suspended

Entering Blood Glucose Readings Manually

You can enter blood glucose readings manually into the PDM. This is particularly helpful if you use a separate blood glucose meter.

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **More actions**, then press **Select**.
2. Choose **Add BG reading**, then press **Select**.
3. Use the **Up/Down Controller** buttons to enter the BG reading from your separate meter.

   TIP To enter a "LOW" reading, press the **Up/Down Controller** buttons down until you reach the minimum value (20); then press down one more time. To enter a "HIGH" reading, press up until you reach the maximum value (500); then press up one more time.
4. Press **Tag** to assign a tag to the reading. Press **OK** when finished. (For an explanation of entering tags, see page 92.)
5. Press **Save** to save the reading.

   Or press **Cancel** to return to the **More actions** menu without saving the reading.

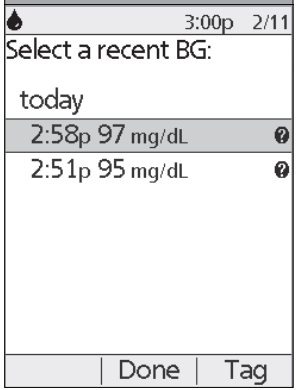
Editing Tags

Within 2 hours of a blood glucose reading, you can remove or change a tag or add one. However, you cannot alter a Control tag.

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **More actions**, then press **Select**.
2. Choose **Assign/Edit BG tags**, then press **Select**.
3. Use the **Up/Down Controller** buttons to choose a reading, then press **Tag** (Figure 7-33). A **User Info/Support** icon (**?**) is shown to the right of any reading to which you have already assigned one or two tags.

   Or press **Done** to return to the **More actions** menu.

Figure 7-33



4. Use the **Up/Down Controller** buttons to choose the first tag you want, then press **Select** (Figure 7-34 on the next page). A diamond icon appears next to selected tags, as in "Pre-meal" in the figure. You can select up to two tags for each BG reading.

Figure 7-34

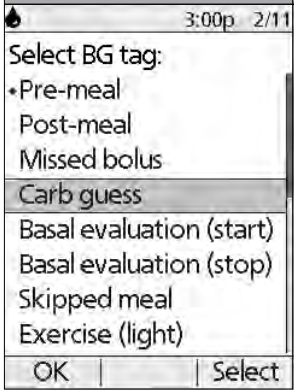


Figure 7-35

5. To remove a selected tag, highlight it and press **Clear**. (The soft key changes from **Select** to **Clear** when you highlight the tag.)
6. Press **OK** to return to the list of readings.
7. If no BG readings have been entered into the PDM within the past 2 hours, you will see the screen in Figure 7-35. Press **OK** to return to the **More actions** menu.

To learn how to manage your list of tags and to add custom tags, see "Manage the blood glucose tags list" in Chapter 6, Using the Personal Diabetes Manager.

n Low and High Blood Glucose Readings

WARNINGS!

"LOW" or "HIGH" blood glucose readings can indicate a potentially serious condition requiring immediate medical attention. If left untreated, this situation can quickly lead to *diabetic ketoacidosis (DKA)*, shock, coma, or death.

Low readings

If your reading is below 20 mg/dL, the PDM displays: "LOW Treat your low BG!" This indicates severe hypoglycemia (low blood glucose).

Low reading with symptoms

If you get a "LOW Treat your low BG!" reading and feel symptoms such as weakness, sweating, nervousness, headache, or confusion, follow your healthcare provider's recommendation to treat hypoglycemia.

Low reading without symptoms

If you get a "LOW Treat your low BG!" reading, but have no symptoms of low blood glucose, then retest with a new test strip on your fingers. If you still get a "LOW Treat your low BG!" reading, perform a control solution test to ensure your system is working properly. If the system is working properly, follow your healthcare provider's recommendation to treat hypoglycemia.

High readings

If your reading is above 500 mg/dL, the PDM displays "HIGH Check for ketones!" This indicates severe *hyperglycemia* (high blood glucose).

High reading with symptoms

If you get a "HIGH Check for ketones!" reading and feel symptoms such as fatigue, thirst, excess urination, or blurry vision, follow your healthcare provider's recommendation to treat hyperglycemia.

High reading without symptoms

If you get a "HIGH Check for ketones!" reading, but have no symptoms of high blood glucose, then retest with a new test strip on your fingers. If you still get a "HIGH Check for ketones!" reading, perform a control solution test to ensure your system is working properly. If the system is working properly, follow your healthcare provider's recommendation to treat hyperglycemia.

NOTE You can add and edit tags for LOW and HIGH BG readings just as you would to any other reading. To add tags, see page 92; to edit tags, see page 94.

n Important Health-Related Information

For additional information, consult your test strip product information sheet.

WARNING **WARNINGS!**

- Severe dehydration and excessive water loss may cause false falsely elevated results. If you believe you are suffering from severe dehydration, consult your healthcare provider immediately.
- Test results below 70 mg/dL mean low blood glucose (hypoglycemia).
- Test results greater than 250 mg/dL mean high blood glucose (hyperglycemia).
- If you get results below 70 mg/dL or above 250 mg/dL, but do not have symptoms of hypoglycemia or hyperglycemia (see Chapter 9, Living with Diabetes), repeat the test. If you have symptoms or continue to get results that fall below 70 mg/dL or above 250 mg/dL, follow the treatment advice of your healthcare provider.
- If you are experiencing symptoms that are not consistent with your blood glucose reading and you have followed all instructions described in this User Guide, call your healthcare provider immediately.
- Blood circulation is different between the finger and other test sites like the upper arm and hand. You may see differences in blood glucose measurements between the other test sites and your finger after eating, taking insulin medication, or exercise.

- You may see changes in blood glucose in blood samples from the finger sooner than in blood samples from alternate sites. Vigorous rubbing of the alternate test sites before lancing helps to minimize these differences.
- Do not use during xylose-absorption testing.
- Measurements obtained from alternate site testing should not be used to calculate insulin doses with the OmniPod System.
- The lancing device is for individual use only and must not be shared. Always use a new, sterile lancet; lancets are for single use only.
- Objects that may be soiled with blood may then transmit pathogens. See "Cleaning and disinfecting" in the Appendix for instructions on how to clean or disinfect your PDM.
- "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm.
- "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html.

CHAPTER 8

Understanding Your Records

n Record Keeping

Record keeping is an important part of successful *diabetes* management. The Personal Diabetes Manager (PDM) helps simplify this task. It automatically stores records of insulin delivery history, *blood glucose* readings, alarms and *carbohydrates*. The PDM can store over 5,000 records or approximately 90 days' worth of information. Once the memory is full, new information begins to replace the oldest information.

If the PDM batteries run out, date and time are at risk. Do NOT remove the old batteries until you have new ones on hand. The PDM protects data in the memory for up to 2 hours after the batteries run out or are removed.

Special symbols in record screens

In the record screens, you may encounter several special symbols:

- Records with a question-mark symbol next to them have additional information available. To see this information, use the **Up/Down Controller** buttons to highlight the record, then press the **User Info/Support** button to view details about that record.
- The record for this item has been "lost."

If the PDM can no longer communicate with an active Pod, then you must activate a new Pod. The PDM may not be able to communicate with the active Pod because of signal interference or because you have discarded the Pod. If you change the Pod without getting a Status update, any "unconfirmed" records will be "lost." If this occurs, the PDM will not display insulin totals for any day containing "lost" records.

4 The record for this item is "unconfirmed."

NOTE When you power on the PDM, it will request a status update from the active Pod and then update the insulin history. If the PDM does not receive a status update from the Pod, the PDM will update history with "unconfirmed" records. The next time the PDM receives a status update, it will update these records.

This insulin delivery item spans midnight. The date given is the start date.

Insulin Delivery Records

The PDM stores:

- *Basal rates* (including any rate changes and temporary basals)
- *Bolus doses* (both normal and extended)
- Dates, times and how long insulin delivery was suspended, and dates and times when it was resumed
- Total daily doses (basal plus boluses) by date

View insulin delivery records

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **My records**, then press **Select**.
2. Choose **Insulin delivery**, then press **Select** (Figure 8-1).

Figure 8-1

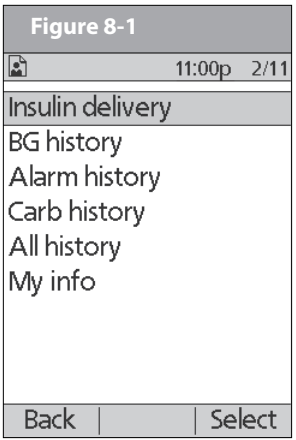
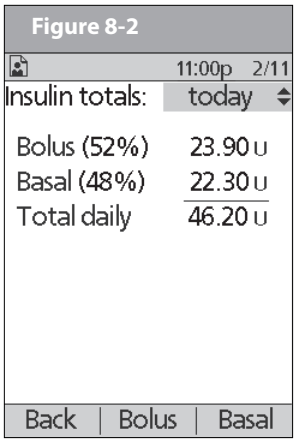


Figure 8-2



The PDM displays a summary of today's information, including total boluses delivered, total basal amount delivered and total daily dose delivered (Figure 8-2). Press the **Up/Down Controller** buttons to view the summary for previous days.

Wherever you see the **?** symbol, press the **User Info/Support** button to see additional information.

3. To review your basal history by day, press **Basal**.

The display shows the basal deliveries that have occurred for the current day, most recent first (Figure 8-3 on the next page). The active basal rate or program is indicated by a diamond icon (u).

Figure 8-3

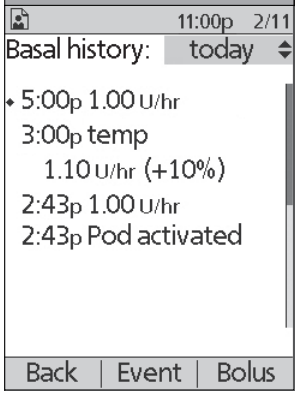


Figure 8-4

For a temporary basal program, the display shows the % adjustment that have been made to the default basal rate (active or current). So, in Figure 8-3, "1.10 temp U/hr (+10%)" means that you delivered a temporary basal of 1.10 units per hour, which was 10% more than the default basal. (Notice that two hours later, the basal rate returns to the default.)

Also, the "Pod activated" entry shows what time you applied a new Pod.

Press the **Up/Down Controller** buttons for earlier or later dates.

Press **Event** to use the **Up/Down Controller** buttons to scroll through the list of information on the screen. Choose a record, then press the **User Info/Support** button to view details about that record. Record details may include insulin delivery, that was interrupted due to a Pod alarm, Pod deactivation, or user cancellation. The screen shows the amount of the bolus or basal that remained undelivered.

4. Press **Day** to return to dates.
5. To review your bolus history by day, press **Bolus**.

   The display indicates whether the bolus was normal or extended (marked "e" in Figure 8-4). Normal and extended boluses are displayed separately even if they were programmed at the same time. Extended boluses are shown with time and duration. If an extended bolus is active, a diamond icon (u) appears next to it. If a bolus was cancelled, only the amount delivered before cancellation is shown.

The amount shown after cancellation may be in 0.05 unit *increments*, even though you may have programmed the bolus increment to be in 0.10 units.

Press the **Up/Down Controller** buttons for different dates.

Press **Event** to use the **Up/Down Controller** buttons to scroll through the list of information on the screen. Press **Day** to return to dates.

n Blood Glucose Records

The PDM stores *blood glucose* records for the past 90 days. You can choose to view individual readings, single-day trends with individual readings, or trends for the previous 7, 14, 30, 60 or 90 days.

View single-day trends

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **My records**, then press **Select**.
2. Choose **BG history**, then press **Select**.

   The PDM displays the current-day trends first (Figure 8-5), including:

   - Number of days and number of blood glucose readings (n)
   - Average blood glucose (Avg BG)
   - Lowest and highest blood glucose (Min/max)
   - The *BG goal* you have set
   - Percentage of readings within the BG goal
   - Percentage of readings above the BG goal
   - Percentage of readings below the BG goal.

Figure 8-5

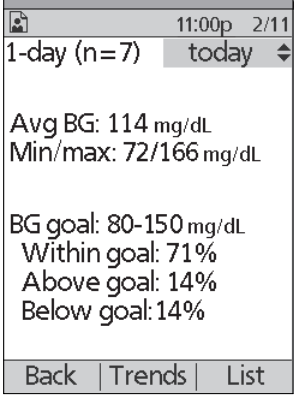
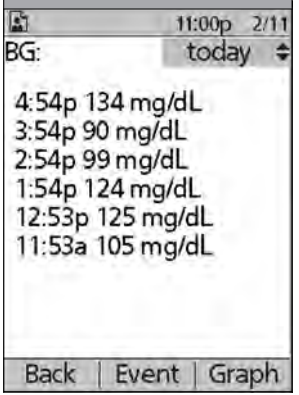


Figure 8-6



NOTE LOW and HIGH readings are included in the number of BG readings (n), but not in calculations or averages.

3. Press **List** to see a list of the current day's readings (Figure 8-6).

In the **List** view, press **Event** to select individual readings. Readings with a question mark icon (**?**) next to them have additional information available (Figure 8-7). To see this information, use the **Up/Down Controller** buttons to choose the reading. Then press the **User Info/Support** button to view details about that reading (Figure 8-8).

Figure 8-7

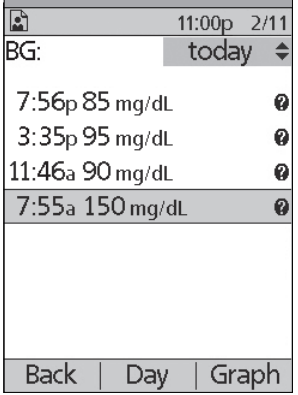


Figure 8-8

4. Press **Close** to return to the **List** view.
5. Press **Graph** to see a graph of the data (Figure 8-9).

View multiple-day trends

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **My records**, then press **Select**.

Figure 8-9

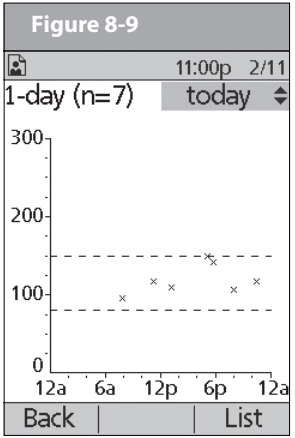
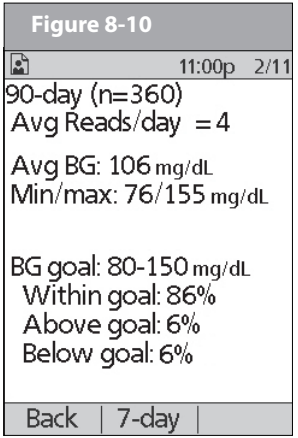


Figure 8-10



2. Choose **BG history**, then press **Select**.
3. Press **Trends** to display blood glucose data for the past 7 days.
4. Continue pressing the middle soft key to view trends for the previous 14, 30, 60 and 90 days.
5. The PDM displays the same details for multiple days as for single days, plus the average number of BG measurements taken per day (Figure 8-10).

   For the 7-, 14- and 30-day trends, press **Graph** to see a graph of the trends (Figure 8-11 on the next page). Graphs are not available for 60- or 90-day trends. Press **Stats** to return to the detail view.

Figure 8-11

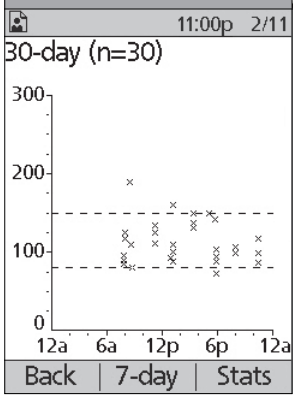


Figure 8-12

6. Press **Back** to return to the single-day trends.

n Alarm Records

The PDM lists the entire alarm history for the OmniPod System. The PDM can store over 90 days' worth of alarm records.

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **My records**, then press **Select**.
2. Choose **Alarm history**, then press **Select**.

   The PDM displays the date, time, and type of each alarm (Figure 8-12).
3. Press the **Up/Down Controller** buttons to see additional screens.
4. Choose an alarm record, then press **User Info/Support** to see more information.

n Carbohydrate Records

The PDM displays the records of carbohydrates you have entered.

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **My records**, then press **Select**.
2. Choose **Carb history**, then press **Select**.

   The PDM displays the date, time and grams of carbohydrate you have entered (Figure 8-13 on the next page).
3. Press the **Up/Down Controller** buttons to see additional days.

   Press **Event** to use the **Up/Down Controller** buttons to scroll through the list of information on the screen. Press **Day** to use the **Up/Down Controller** buttons for dates.

Figure 8-13

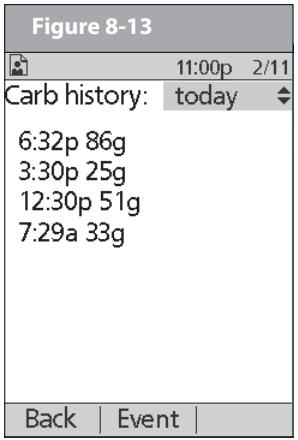
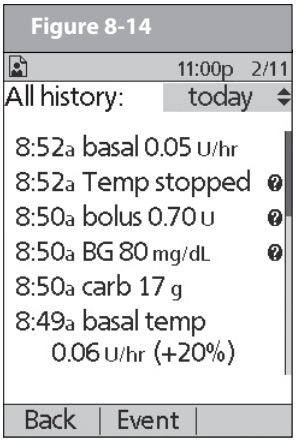


Figure 8-14



All Records

The PDM displays the combined insulin delivery, blood glucose, alarm and carbohydrate records.

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **My records**, then press **Select**.
2. Choose **All history**, then press **Select**.

   The PDM displays all history for the most recent date (Figure 8-14).
3. Press the **Up/Down Controller** buttons to see additional days.

   Press **Event** to use the **Up/Down Controller** buttons to scroll through the list of information on the screen. Press **Day** to use the **Up/Down Controller** for dates.

User Information/Support

You or your healthcare provider may have entered personal contact information during your start-up visit. To view this information, press the **User Info/Support** button (to the right of the **Power** button) while on the **Home** screen. Or follow the steps below to view the information. You can add or change the user information at any time.

You may want to include your name, address, phone, e-mail address, emergency contact and phone, doctor's or healthcare provider's name and phone, prescription numbers or other information.

The user information screen also displays product information for your OmniPod System (make, model, serial number). You cannot change this information.

TIP The **User Info/Support** icon is also displayed on the suggested bolus screen. For information about the support information displayed on these screens, see Chapter 4, Understanding and Delivering Bolus Doses.

Add or change user information

NOTE The first line of **My Info** displays the information that was entered for the **ID** screen during your PDM setup. For information on editing this line, see Chapter 6, Using the Personal Diabetes Manager, "Customize the Personal Diabetes Manager."

1. On the **Home** screen, use the **Up/Down Controller** buttons to choose **My records**, then press **Select**.
2. Choose **My info**, then press **Select**.
3. Choose an existing line or **[My info]** (Figure 8-15), then press **Edit**.
4. Press the **Up/Down Controller** buttons to scroll through the list of characters. An up-and-down arrow symbol (⇕) on the screen indicates the character you are changing.
5. Press the middle soft key to move the underscore to the next character.

Figure 8-15

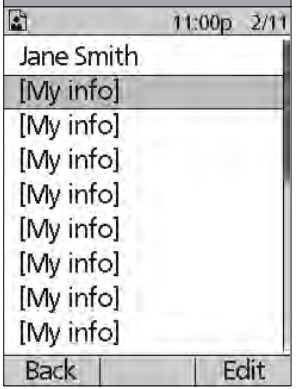
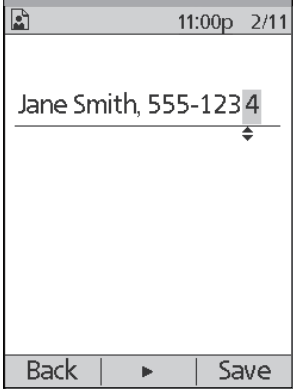


Figure 8-16



6. Enter each character one at a time. For example, if you want to enter your address, you might enter 5, 6, 5, [space], M, a, i, n, [space], S, t, [period]. (A blank character or space is the first and last option in the scrolling menu.)

   For your healthcare provider and local phone number, you might enter J, a, n, e, [space], S, m, i, t, h, [comma], [space], 5, 5, 5, [hyphen], 1, 2, 3, 4 (Figure 8-16).
7. Press **Save**.
8. Repeat steps 3–7 for each line of personal information you want to enter or change. Twenty lines are available.

CHAPTER 9

Living with Diabetes

Your Role: Safely Using the OmniPod System

Before deciding on the OmniPod® Insulin Management System, you and your *healthcare provider* discussed the advantages and benefits of the OmniPod System, as well as the responsibilities that come with *insulin* pump therapy. Remember: safe use begins and ends with you. If you have questions or doubts about being able to safely use the OmniPod System at any time, consult your healthcare provider immediately.

Most problems are easily avoided by:

- Learning all you can about successful *diabetes* management.
- Being actively involved in your treatment.
- Checking your *blood glucose* levels frequently.
- Washing your hands and disinfecting *infusion sites* to reduce the possibility of infection.
- Being aware of the signs of *hypoglycemia* (low blood glucose), *hyperglycemia* (high blood glucose), and *diabetic ketoacidosis* (DKA). (See "Avoid Lows, Highs and DKA" later in this chapter.)
- Keeping a diabetes emergency kit with you at all times. (See "Prepare for Emergencies" later in this chapter.)
- Knowing how to contact your healthcare provider in case of an emergency.

If you are unable to use the OmniPod Insulin Management System according to instructions, you may be putting your health and safety at risk. Talk with your healthcare provider if you have questions or concerns about using the OmniPod System.

Daily Diabetes Management Activities

To ensure proper OmniPod System operation and your continued good health:

- Check your blood glucose frequently
- Inspect the infusion site daily

Check your blood glucose frequently

When you routinely check your *blood glucose level*, you can identify and treat high or low blood glucose before it becomes a problem (see "Avoid lows, highs, and DKA" later in this chapter).

Check your blood glucose (BG):

- At least 4 to 6 times a day: when you wake up, before every meal, and before going to bed
- Whenever you feel nauseated or sick
- Before driving a car
- Whenever your blood glucose has been running unusually high or low
- If you suspect that your blood glucose is high or low
- Before, during, and after exercise
- As directed by your healthcare provider

Inspect the infusion site daily

At least once a day, use the Pod's viewing window to inspect the infusion site. Check the site for signs of infection, such as pain, swelling, redness, discharge or heat.

If an infusion site shows signs of infection:

1. Immediately remove the Pod and apply a new one at a different site (see Chapter 5, Using the Pod).
2. Contact your healthcare provider.

Treat the infection according to instructions from your healthcare provider. (Refer to Chapter 5, Using the Pod, for how to prepare and care for a site.)

Consider making infusion site checks a part of your regular daily routine (like showering or brushing your teeth). That way, it's easy to remember. Verify there is no wetness or scent of insulin, which may indicate the cannula has dislodged.

If you observe blood in the cannula, check your blood glucose more frequently to ensure insulin delivery has not been affected. If you experience unexpected elevated blood glucose levels, change your Pod.

Prepare for Emergencies

Keep an emergency kit with you at all times to quickly respond to any diabetes emergency. The kit should include:

- Several new, sealed Pods
- Extra new PDM batteries (at least two AAA alkaline)
- A vial of rapid-acting U-100 insulin (See the warning on page x of the Introduction for insulins approved for use in the OmniPod System.)
- Syringes for injecting insulin
- Instructions from your healthcare provider about how much insulin to inject if delivery from the Pod is interrupted
- Blood glucose test strips
- Ketone test strips
- Lancing device and lancets
- Glucose tablets or another fast-acting source of carbohydrate
- Alcohol prep swabs
- A copy of the letter from your healthcare provider for airline security (see "Minimize airport security delays" later in this chapter)
- Phone numbers for your healthcare provider and/or doctor in case of an emergency
- Glucagon kit and written instructions for giving an injection if you are unconscious (see "Avoid Lows, Highs and DKA" later in this chapter)

Ask your healthcare provider to help you develop plans for handling emergency situations, including what to do if you cannot reach your healthcare provider.

Water and Your Pod

The Pod is waterproof to a depth of 25 feet for up to 60 minutes (IPX8). After the Pod gets wet, rinse it off with clean water and dry it with a towel.

Do NOT expose your Pod to water at depths greater than 25 feet or for longer than 60 minutes. Check the infusion site often to make sure the Pod and soft cannula are securely applied and in place. If the cannula is not properly inserted, hyperglycemia may result.

The Personal Diabetes Manager (PDM) is not waterproof. Do NOT place it in or near water.

n Traveling and Vacationing

Plan for changing time zones

If you're planning a vacation or business trip to a different time zone, you may need to adjust your *basal rate* programs. For changes of just a few hours, basal rate adjustments are minor and easy to calculate. For long-distance travel, however, figuring out the correct program can be more challenging. Your health-care provider can help with these adjustments.

Take enough supplies

Keeping your emergency kit with you during trips or vacations is especially important (see "Prepare for Emergencies" on page 108). It may be difficult or impossible to get insulin or supplies in an unfamiliar place. If traveling by air, be sure to pack your supplies in your carry-on luggage. When packing for travel, take more supplies than you think you'll need. Be sure to include:

- Diabetes emergency kit packed in your carry-on luggage
- Enough Pods for your trip, plus a backup supply
- Extra new PDM batteries
- Additional blood glucose meter
- Insulin syringes or pens in case you need injections
- Several vials of insulin or insulin cartridges if you use a pen
- Glucagon kit (Make sure any person you are traveling with knows how to give the injection.)
- Alcohol prep swabs
- Written prescriptions for all medications and supplies (Generic medications may be easier to find than brand names outside the U.S.)

When you travel outside the country or for long periods of time, be sure to take extra Pod supplies. Call 800-591-3455 (from outside the United States: 781-457-5098) to order additional supplies for your trip.

Minimize airport security delays

With changing airport security checks and screening procedures, you may have questions on how this impacts traveling with your diabetes supplies. Below you will find more information on prepping for travel and what you can expect when going through security checkpoints.

Travel Preparation

- Review the TSA website for travel updates
- Pack extra supplies and hypoglycemia treatments
- Carry contact information for your physician
- Arrive at the airport 2-3 hours prior to your flight

To ensure airport security checks run smoothly, be sure you have the following items easily accessible:

- All diabetes supplies in your carry-on luggage

- A signed letter from your healthcare provider explaining you need to carry insulin supplies and OmniPod equipment
- Prescriptions for all medications and supplies with original prescription labels

Screening Procedures

The TSA offers the option of requesting a visual inspection of your medical supplies rather than putting them through the X-ray. This must be requested before the screening process begins. Your medical supplies should be ready in a separate bag when you approach the Security Officer.

In order to prevent contamination or damage to your supplies, the TSA states that you should be asked at the security checkpoint to display, handle, and repack your own supplies during the visual inspection process. Any medication and/or associated supplies that cannot be cleared visually must be submitted for X-ray screening.

If you're concerned or uncomfortable about going through the walk-through metal detector, the TSA states that you should notify the Security Officer that you're wearing a pump and would like a full-body pat-down and a visual inspection of your pump instead. You should also advise the Security Officer that the insulin pump cannot be removed because it is inserted with a catheter (needle) under the skin.

Visit the TSA Contact Center if you have any further questions or concerns.

If the security detector goes off, tell the security screener that you have diabetes and wear an insulin Pod (pump).

Pods and PDMs can safely pass through airport X-ray machines (see the "OmniPod System Notice Concerning Interference" in the Appendix).

Keep supplies accessible

On airplanes and trains, keep these items with you, rather than checking them:

- Personal Diabetes Manager (PDM)
- An emergency kit
- Vials of insulin (cargo area temperatures may affect insulin)
- A copy of your healthcare provider's letter (see "Minimize airport security delays")
- Prescriptions for insulin and supplies
- Snacks, in case food is not available
- Bottled water (especially on planes) to prevent dehydration

The name and phone number of a physician at your final destination, in case of emergency.

n Avoid lows, highs, and DKA

You can avoid most risks related to using the OmniPod System by practicing proper techniques and by acting promptly at the first sign of trouble. You can avoid potential problems by knowing the signs of hypoglycemia (low blood glucose), hyperglycemia (high blood glucose), and diabetic ketoacidosis (DKA). The easiest and most reliable way to avoid these conditions is to check your blood glucose often.

General precautions

- Keep careful records and discuss changes and adjustments with your healthcare provider.
- Tell your healthcare provider if you have extreme highs or lows, or if highs or lows are occurring more often than usual.
- If you have technical problems with your OmniPod System and cannot resolve them, do not hesitate to call Customer Care.

Hypoglycemia (Low Blood Glucose)

Hypoglycemia can occur even when a Pod is working properly. Never ignore the signs of low blood glucose (no matter how mild). If left untreated, severe hypoglycemia can cause seizures or lead to unconsciousness. If you suspect that your blood glucose level is low, check your BG level to confirm.

Symptoms of hypoglycemia

Never ignore these symptoms:

- Shakiness
- Fatigue
- Unexplained sweating
- Cold, clammy skin
- Weakness
- Blurred vision or a headache
- Sudden hunger
- Rapid heart rate
- Confusion
- Tingling in the lips or tongue
- Anxiety

WARNING

Hypoglycemia unawareness is a condition in which you do not realize when your blood glucose level is low. If you are prone to hypoglycemia unawareness, you may want to use the OmniPod System's blood glucose reminder and check your blood glucose more frequently. See "Alerts and Reminders" in Chapter 6, Using the Personal Diabetes Manager, for how to set the reminder.

To avoid hypoglycemia (low blood glucose)

WARNING

Make sure your blood glucose is at least 100 mg/dL before driving or working with dangerous machinery or equipment. Hypoglycemia may cause you to lose control of a car or dangerous equipment. Also, when you focus intently on a task, you may miss the symptoms of hypoglycemia.

- Work with your healthcare provider to establish individualized *blood glucose targets* and guidelines.
- Keep a fast-acting *carbohydrate* with you at all times to respond quickly to low blood glucose. Examples of fast-acting carbs are glucose tablets, hard candies or juice.
- Teach your friends, family members and colleagues to recognize the signs of hypoglycemia, so they can help if you develop *hypoglycemia unawareness* or a severe adverse reaction.
- Keep a glucagon injection kit with your emergency supplies. Teach friends and family members how to give a glucagon injection in case you have severe hypoglycemia and become unconscious.

NOTE

Periodically check the expiration date of your glucagon kit to make sure it has not expired.

TIP

Always carry medical identification (emergency wallet card) and wear an emergency medical necklace or bracelet such as the Medic Alert tag. (See the end of the Appendix for address, telephone and website information for obtaining these items.)

Again, ***frequent blood glucose checks are the key to avoiding potential problems***. Detecting low blood glucose early lets you treat it before it becomes a problem.

Check with your healthcare provider for guidance in any and all areas listed above.

To treat hypoglycemia (low blood glucose)

Any time your blood glucose is low, treat immediately. Check it every 15 minutes while you are treating.

Even if you cannot check your blood glucose, do NOT wait to treat symptoms of hypoglycemia, especially if you are alone. Waiting to treat symptoms could lead to severe hypoglycemia, which can quickly lead to shock, coma or death.

1. If blood glucose is below 70 mg/dL, eat or drink 15 grams of fast-acting carbohydrate, such as glucose tablets, juice, or hard candy (see "How much is 15 grams of carbohydrate?" below).

Do NOT use chocolate or candy bars to treat low blood glucose. Their fat content slows down glucose absorption.

2. Check blood glucose again after 15 minutes.
3. If blood glucose remains low, eat another 15 grams of carbohydrate. Contact your healthcare provider as needed for guidance.
4. Repeat steps 2 and 3 until blood glucose is within the *BG goal*.
5. Investigate possible cause for hypoglycemia to avoid similar problems in the future (see "Possible causes of hypoglycemia (low blood glucose)" on the next page).

How much is 15 grams of carbohydrate?

Examples of fast-acting foods:

Three 5-gram glucose tablets, or four 4-gram tablets

4 ounces (118 milliliters) of apple or orange juice

6 Lifesavers™ or similar hard candy

1/2 can of regular (non-diet) soda

2 tablespoons (30 milliliters) of table sugar, honey or corn syrup

Teach people you trust (like family members and close friends) how to give a glucagon injection. You will need to rely on them to give it to you if you have severe hypoglycemia and become unconscious. Include a copy of the glucagon instructions in your emergency kit and periodically review the procedure with family and friends.

Possible causes of hypoglycemia (low blood glucose)

Possible cause of low blood glucose	*Suggested action*
Incorrect basal program	Confirm that correct basal program is active. Confirm that PDM time is set correctly. Consult your healthcare provider about adjusting your basal programs or using a temporary (temp) basal rate.
Incorrect bolus timing ***Bolus too large***	Take bolus with food. Check blood glucose before giving meal bolus; if necessary, adjust bolus. Check bolus size and timing. Do NOT overcorrect for post-meal glucose levels. Check carb intake. Consult healthcare provider for guidance.
Incorrect target blood glucose levels ***Incorrect correction factor (sensitivity factor)*** ***Incorrect insulin-to-carb (IC) ratio***	Consult healthcare provider about refining these settings as needed.
Prone to severe hypoglycemia ***Hypoglycemia unawareness***	Consult healthcare provider about hypoglycemia unawareness and about raising target blood glucose levels.
Unplanned physical activity	If blood glucose is below 100 mg/dL, eat a snack before activity. Consult your healthcare provider about using a temporary (temp) basal rate.

Possible cause of low blood glucose	*Suggested action*
Prolonged or intense exercise	Adjust insulin delivery as instructed by your healthcare provider. Check blood glucose before, during and after activity and treat as necessary. NOTE Effects of exercise can last several hours—even a full day—after activity ends. Consult your healthcare provider about adjusting your basal programs or using a temporary (temp) basal rate.
Low carbohydrate intake prior to activity	Consume carbohydrate before activity, especially if you have not decreased insulin beforehand.
Alcohol consumption	Check blood glucose before going to bed. Consult healthcare provider for guidance.

Hyperglycemia (high blood glucose)

Insulin Pods use rapid-acting insulin, so you have no long-acting insulin in your body. If an *occlusion* (interruption of insulin delivery from the Pod) occurs, your blood glucose can rise rapidly.

An occlusion may result from a blockage, Pod malfunction or from using old or inactive insulin. If insulin delivery is interrupted by an occlusion, check your blood glucose level and follow the treatment guidelines established by your healthcare provider. Hyperglycemia could result if appropriate actions are not taken.

Symptoms of hyperglycemia (high blood glucose)

- Fatigue
- Frequent urination, especially during the night
- Unusual thirst or hunger
- Unexplained weight loss
- Blurred vision
- Slow healing of cuts or sores

Hyperglycemia symptoms can be confusing. Always check your blood glucose before you treat for hyperglycemia.

To avoid hyperglycemia (high blood glucose)

Check your blood glucose at least 4–6 times a day (when you wake up, before each meal, and before going to bed). In addition, always check it:

- If you feel nauseated or sick
- Before driving a car
- Whenever your blood glucose has been running unusually high or low
- If you suspect that your blood glucose is high or low
- Before, during and after exercise
- As directed by your healthcare provider

To treat hyperglycemia (high blood glucose)

Always check your blood glucose levels frequently while treating hyperglycemia. You don't want to over-treat the condition and cause your BG level to drop too far.

1. Check your blood glucose level. The result will help you to find out how much insulin is needed to return your blood glucose to the BG goal.
2. If your blood glucose is 250 mg/dL or above, check for ketones. If ketones are present, follow your healthcare provider's guidelines.
3. If ketones are not present, take a correction bolus as prescribed by your healthcare provider.
4. Check blood glucose again after 2 hours.
5. If blood glucose levels have not decreased, take a second bolus by injection, using a sterile syringe. Ask your healthcare provider whether to inject the same amount of insulin as in step 3.
6. If you feel nauseated at any point, check for ketones and call your healthcare provider immediately (see "Diabetic ketoacidosis (DKA)" later in this chapter).
7. If blood glucose remains high after another 2 hours (a total of 4 hours), replace the Pod. Use a new vial of insulin to fill the new Pod. Then:
   - Contact your healthcare provider for guidance.
   - Drink eight ounces of water every 30 minutes until blood glucose is within BG goal.

If you need emergency attention, ask a friend or family member to take you to the emergency room or call an ambulance. Do NOT drive yourself.

8. Investigate possible cause for hyperglycemia to avoid similar problems in the future [see "Possible causes of hyperglycemia (high blood glucose)"].

Possible causes of hyperglycemia (high blood glucose)

Possible cause of high blood glucose	*Suggested action*
Expired insulin	Deactivate and remove used Pod. Apply a new Pod filled from a new vial of insulin.
Insulin exposed to extreme temperatures	
Infusion site in or near a scar or mole	Deactivate and remove used Pod. Apply a new Pod in a different location.
Infected infusion site	Deactivate and remove used Pod. Apply a new Pod in a different location and consult your healthcare provider.
Dislodged cannula	Deactivate and remove used Pod. Apply a new Pod in a different location. NOTE Avoid sites near a waistband, belt, or other areas where friction may dislodge the cannula.

Possible cause of high blood glucose	*Suggested action*
Empty Pod	Deactivate and remove used Pod. Apply a new Pod in a different location.
Incorrect basal program	Confirm that correct basal program is active. Confirm that PDM time is set correctly. Consult your healthcare provider about adjusting your basal programs or using a temporary (temp) basal rate.
Incorrect bolus timing	Check carb intake. Take bolus with food. Check blood glucose before giving meal bolus; if necessary, adjust bolus. Consult healthcare provider for guidance.
Bolus too small	

Possible cause of high blood glucose	*Suggested action*
High-protein or high-fat meal	Calculate protein/fat intake and account for it in your bolus timing and bolus type. Consult healthcare provider about using the extended bolus option.
Less activity than normal	Consult your healthcare provider about adjusting your basal programs or using a temporary (temp) basal rate.
Blood glucose value greater than 250 mg/dL (with ketones present) before exercise	Do NOT exercise when ketones are present. (Blood glucose increases with exercise when ketones are present.) Consult healthcare provider for guidance.
Infection or illness	See "Sick days" later in this chapter.
Medication change	Consult your healthcare provider about sick day guidelines and about medication changes.
Weight loss or gain	Consult your healthcare provider for guidance.
Menstrual cycle	
Pregnancy	

NOTE Check with your healthcare provider for guidance on any of the causes or suggested actions above.

Diabetic ketoacidosis (DKA)

Insulin Pods use rapid-acting insulin, so you have no long-acting insulin in your body. If insulin delivery from the Pod is interrupted (an occlusion), your blood glucose can rise rapidly and lead to diabetic ketoacidosis (DKA). DKA is a serious—but totally preventable—emergency that can occur if you ignore high blood glucose levels.

If left untreated, DKA can cause breathing difficulties, shock, coma, and eventually death.

Symptoms of DKA

- Nausea and vomiting
- Abdominal pain
- Dehydration
- Fruity-smelling breath
- Dry skin or tongue
- Drowsiness
- Rapid pulse
- Labored breathing

The symptoms of DKA are much like those of the flu. Before assuming you have the flu, check your blood glucose and check for ketones to rule out DKA.

To avoid DKA

The easiest and most reliable way to avoid DKA is by **checking your blood glucose at least 4–6 times a day.** Routine checks allow you to identify and treat high blood glucose before DKA develops.

To treat DKA

- Once you have begun treatment for high blood glucose, check for ketones. Check for ketones any time your blood glucose is 250 mg/dL or above.
- If ketones are negative or trace, continue treating for high blood glucose.
- If ketones are present, and you are feeling nauseated or ill, immediately call your healthcare provider for guidance.
- If ketones are positive, but you are not feeling nauseated or ill, replace the Pod, using a new vial of insulin.
- Check blood glucose again after 2 hours. If blood glucose level has not declined, immediately call your healthcare provider for guidance.

If you need emergency attention, ask a friend or family member to take you to the emergency room or call an ambulance. Do NOT drive yourself.

Handling Special Situations

Sick days

Any physical stress can cause your blood glucose to rise, and illness is a physical stress. Your healthcare provider can help you make a plan for sick days. The following are only general guidelines.

When you are ill, check your blood glucose more often (at least once every 2 hours) to avoid DKA. The symptoms of DKA are much like those of the flu. Before assuming you have the flu, check your blood glucose to rule out DKA (see "Diabetic ketoacidosis (DKA)" earlier in this chapter).

To handle sick days

- Treat the underlying illness to promote faster recovery.
- Eat as normally as you can.
- Adjust bolus doses, if necessary, to match changes in meals and snacks.
- Always continue your basal insulin, even if you are unable to eat. Contact your healthcare provider for suggested basal rate adjustments during sick days.
- Check your blood glucose every 2 hours and keep careful records of results.
- Check for ketones when blood glucose is 250 mg/dL or higher.
- Follow your healthcare provider's guidelines for taking additional insulin on sick days.
- Drink plenty of noncaffeinated fluids to prevent dehydration.

If you are well enough to eat, drink sugar-free beverages. However, if you are too sick to eat solid foods, alternate between sugar-free beverages and those containing sugar.

- Call your healthcare provider immediately if you have:
  - Persistent nausea
  - Vomiting for more than 2 hours
  - High blood glucose or ketones that stay high even though you take extra insulin
  - Low blood glucose with nausea and vomiting

Exercising, playing sports, or working hard

Check your blood glucose levels before, during and after exercising, playing sports, or doing unusually hard physical labor.

The Pod's adhesive keeps it securely in place for up to 3 days. However, if necessary, several products are available to enhance adhesion. Ask your healthcare provider about these products.

Avoid getting body lotion, creams, or oils near the infusion site; these products may loosen the adhesive.

For some contact sports, you may want to remove the Pod.

Be sure to check your blood glucose levels before removing the Pod and after applying a new one. Pods are designed for one-time use. Do not attempt to reapply a used Pod.

If possible, avoid wasting Pods by planning removal times that coincide with a scheduled Pod replacement.

If you will need to remove the Pod for more than 1 hour, ask your healthcare provider to recommend appropriate guidelines.

X-rays, MRIs, and CT scans

The Pod and PDM may be affected by strong radiation or magnetic fields. Before having an X-ray, MRI, or CT scan (or any similar test or procedure), remove your Pod and put it and the PDM outside the treatment area. Check with your healthcare provider on Pod removal guidelines.

The Pod and PDM can tolerate common electromagnetic and electrostatic fields, including airport security and cellular phones.

Surgery or hospitalization

For scheduled surgeries or hospitalization, you should tell the doctor/surgeon or hospital staff about your insulin Pod. It may be necessary to remove it for certain procedures or treatments. Remember to replace the basal insulin that was missed while the Pod was removed. Your healthcare provider can help you prepare for these situations.

Always carry medical identification and wear an emergency medical necklace or bracelet such as the Medic Alert tag.

CHAPTER 10

Alerts and Alarms

n Safety Checks

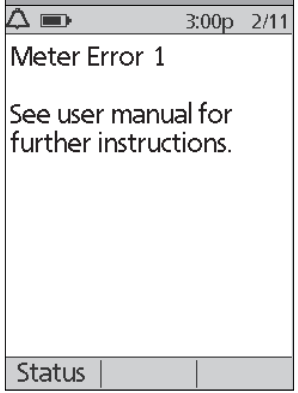
The OmniPod System has a very important safety feature: It can check its own functions and let you know when something needs attention. When you turn on the Personal Diabetes Manager (PDM), the System automatically performs a series of safety checks. (Refer to page 57 for detailed instructions. The **ID** screen must be confirmed before you can check Pod status.) To make you aware of a serious or potentially serious condition, the System sounds an alarm and displays an on-screen message. The message has instructions for taking care of the alarm condition. Alarm conditions are easy to handle. They are not a problem if you attend to them promptly.

n Blood Glucose Meter Alerts

These alerts let you know about an error in the blood glucose meter, test strip, sample, or results. The PDM beeps and displays an error message number, as in Figure 10-1.

If you are having symptoms that are not consistent with your blood glucose test and you have followed all instructions described in this *User Guide*, call your healthcare professional.

Figure 10-1



The following table explains what the message could mean and what you should do.

Alert error message	*Possible causes*	*Action*
Meter Error 1 See user manual for further instructions.	• Blood sample is too small. • Problem with the test strip. • Problem with the meter. • Very low *blood glucose*: less than 20 mg/dL.	1. If you have symptoms, such as weakness, sweating, nervousness, headache or confusion, follow the recommendations of your *healthcare provider* for treating *hypoglycemia*. 2. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of the test strip vial, retest using blood and a new test strip. 3. If the control solution test does not work, or the error persists, call Customer Care.
Meter Error 2 See user manual for further instructions.	• Problem with the test strip. • Problem with the meter. • Very high blood glucose: above 500 mg/dL. • HIGH control solution applied when temperature is too cold. (This applies only to control solution labeled HIGH.)	1. If you have symptoms, such as thirst, fatigue, excess urination or blurry vision, follow the recommendations of your healthcare provider for treating *hyperglycemia*. 2. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of the test strip vial, retest using blood and a new test strip. 3. If the control solution test does not work or the error persists, call Customer Care.

Alert error message	*Possible causes*	*Action*
Meter Error 3 See user manual for further instructions.	• Incorrect test procedure. For example, putting blood on the test strip before inserting the test strip into the meter or applying blood before the Blood Drop and Test Strip symbols display. • Problem with the test strip. • Problem with the meter.	1. Be sure you see the Blood Drop and Test Strip symbols on the display screen before you apply blood or control solution. 2. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of the test strip vial, retest using blood and a new test strip. 3. If the control solution test does not work or the error persists, call Customer Care.
Meter Error 4 See user manual for further instructions.	• Problem with the test strip. • Problem with the meter.	1. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of the test strip vial, retest using blood and a new test strip. 2. If the control solution test does not work or the error persists, call Customer Care.
Meter Error 6 See user manual for further instructions.	• Blood sample was applied while the code number was being changed.	1. Retest using a new test strip. Do not press any buttons or *Soft Keys* while applying blood or control solution to the test strip. 2. If the error persists, call Customer Care.

n Alarms

The OmniPod System provides alarms to make you aware of serious or potentially serious conditions. When a condition occurs that requires your attention an Advisory Alarm or a Hazard Alarm will sound. Advisory alarms beep intermittently and inform you about a condition that requires your attention. During an alarm the PDM will display an on-screen message with instructions for taking care of the alarm condition. Be sure to respond to all alarms when they occur.

Details on how to handle an Advisory or a Hazard Alarm are below:

Many alarms (such as ***Auto-off***) will escalate and result in deactivation of the active Pod if ignored. Be sure to respond to all alarms when they occur.

Hazard alarms are continuous tones. If the alarm is not acknowledged immediately, the Pod will periodically generate an intermittent alarm tone and then return to the continuous tone.

Advisory Alarms

Advisory alarms tell you about a condition that requires your attention. Each advisory alarm beeps intermittently. When you hear an advisory alarm, first turn on the PDM to display the **Status** screen. The PDM communicates with the Pod, if necessary, and the screen displays a message describing the alarm and how to resolve it. All advisory alarms are time sensitive and require a response. Some advisory alarms escalate to hazard alarms if you do not respond within a certain time period (as noted in the following table).

Some advisory alarms are controlled by levels you set in the **Settings** screen. One example is the level at which the ***Low reservoir volume*** alarm sounds.

Hazard Alarms

Hazard alarms occur either when the Pod is in a very serious condition or something is wrong with the PDM. Follow the instructions in the message to fix the alarm situation. For details, see the following table.

When a hazard alarm occurs in the Pod, all insulin delivery stops. Failing to address the situation could result in hyperglycemia. If you had a temp basal or extended bolus running when the hazard occurred, the PDM will remind you of this.

Due to the serious nature of hazard alarms, you must act promptly to resolve them.

1. Acknowledge the alarm condition by pressing **OK**, which silences the alarm.
2. Deactivate and remove the active Pod (see Chapter 5, Using the Pod).
3. Activate and apply a new Pod (see Chapter 5, Using the Pod).

If you ever need to return the PDM for repair or replacement, contact your healthcare provider for instructions on going back to treatment by injections.

Use the form at the end of this *User Guide* to write down all your settings from the Setup Wizard. If you ever need to reset your PDM, having these settings handy will make setup very easy.

Alarm	*Type*	*Source*	*Beep Pattern*	*Action*
End of insulin suspend. Press **OK** to resume basal rate delivery.	Advisory Alarm	Pod and PDM	2 sets of beeps every minute for 3 minutes. Repeats every 15 minutes until insulin delivery is resumed.	Press **OK** to resume insulin delivery at programmed *basal rate*. WARNING: Insulin delivery will not resume until you press **OK**. If you do not press **OK** to resume insulin delivery, you could develop hyperglycemia (high blood glucose).
Auto-off alert	Advisory Alarm	Pod and PDM	2 sets of beeps every minute for 15 minutes. Escalates to ***Auto-off*** hazard alarm if not acknowledged within 15 minutes.	Press **OK** to acknowledge. WARNING: The Auto-off alert will escalate to a hazard alarm if ignored and will result in the deactivation of your active Pod. Be sure to respond to the alert when it occurs.

Alarm	*Type*	*Source*	*Beep Pattern*	*Action*
Auto-off. Remove Pod now.	Hazard Alarm	Pod and PDM	Continuous tone.	Pod has been deactivated. Insulin delivery has stopped. Press **OK** to acknowledge. Change Pod. Check blood glucose.
Low reservoir. Replace Pod soon. (This is based on the volume level you selected.)	Advisory Alarm	Pod and PDM	2 sets of beeps every minute for 3 minutes. Repeats every 60 minutes until acknowledged. Escalates to ***Empty reservoir*** hazard alarm when empty.	Press **OK** to acknowledge. The ***Low reservoir*** alert will escalate to an ***Empty reservoir*** hazard alarm when insulin is depleted. Be sure to respond to the alert when it first occurs.
Empty reservoir. Insulin delivery stopped. Change Pod now.	Hazard Alarm	Pod and PDM	Continuous tone.	This alarm occurs when the Pod's reservoir is out of insulin. Press **OK** to acknowledge. Change Pod. Check blood glucose.

Alarm	*Type*	*Source*	*Beep Pattern*	*Action*
Pod expiration advisory. Change Pod now.	Advisory Alarm	Pod and PDM	2 sets of beeps repeat periodically. Repeats every 15 minutes during the last hour of the Pod's life and is independent of the Expiration notification that you can set. (See Chapter 6 "Using the PErsonal Diabetes Manager"). Escalates to ***Pod expired*** hazard alarm.	Press **OK** to acknowledge. Change Pod. (See Chapter 5, Using the Pod.)
Pod expired. Insulin delivery stopped. Change Pod now.	Hazard Alarm	Pod	Continuous tone.	This alarm occurs when the Pod has reached the end of its operating life. Press **OK** to acknowledge. Change Pod. Check blood glucose.
Stuck key detected. Check **Home** button to resolve. For technical support refer to your *User Guide*.	Advisory Alarm	PDM	2 sets of beeps every 5 minutes.	Check the key described on the screen. (In this example, the stuck key is the **Home** button.) Press the key to unstick it. If this does not work, call Customer Care.

Alarm	*Type*	*Source*	*Beep Pattern*	*Action*
Occlusion detected. Insulin delivery stopped. Change Pod now.	Hazard Alarm	Pod and PDM	Continuous tone.	Press **OK** to acknowledge. Change Pod. Check blood glucose.
Pod Error. Insulin delivery stopped. Change Pod now.	Hazard Alarm	Pod	Continuous tone.	This alarm occurs when the Pod detects an unexpected error. Press **OK** to acknowledge. Change Pod. Check blood glucose.
PDM Error. Remove Pod now. Call Customer Care: 800-591-3455.	Hazard Alarm	PDM	Continuous tone.	This alarm occurs if an unexpected error is detected in the PDM. Press **OK** to acknowledge. Remove Pod. Call Customer Care immediately. Check blood glucose.

Alarm	*Type*	*Source*	*Beep Pattern*	*Action*
PDM Error. Memory corruption. Press "**OK**" to reset PDM and delete all user settings. History records will not be deleted.	Hazard Alarm	PDM	Continuous tone.	This alarm occurs after the PDM is reset and a memory corruption error occurs. Press **OK** to acknowledge. Change Pod. Check blood glucose.
System Error. Remove Pod now. Call Customer Care: 800-591-3455.	Hazard Alarm	Pod or PDM	Continuous tone.	This alarm occurs if an unexpected error is detected in the Pod or PDM. Press **OK** to acknowledge. Remove Pod. Call Customer Care immediately. Check blood glucose.
PDM Error. Press **OK** to reset clock.	Hazard Alarm	PDM	Continuous tone.	This alarm occurs after the PDM is reset, indicating that the time and date must be reset. Press **OK** to acknowledge. Reset clock. Check blood glucose.

Alarm	Type	Source	Beep Pattern	Action
Pod deactivation required. Press "Ok" to deactivate.	Hazard Alarm	PDM	Continuous tone.	This alarm occurs after a PDM error occurs that requires the user to reset the date and time. Press **OK** to acknowledge. Change Pod. Check blood glucose.

n Manual Shut-off of a Hazard Alarm

If you respond to a hazard alarm but the PDM cannot communicate with the Pod to acknowledge or shut off the alarm, you can shut off the alarm manually.

1. Remove the Pod from your body if you have not already done so.
2. Press the end of a paper clip or similar item straight down into the manual alarm shut-off port (Figure 10-2) on the bottom of the Pod. The port can be found by peeling back the adhesive pad from the bottom of the Pod at the square end. The alarm shut-off port is to the right of the fill port.
3. Press the paper clip straight down into the manual alarm shut off port until the alarm stops and can no longer be heard. Then discard the Pod according to local waste disposal regulations.
4. The Reset Button is located in the PDM's battery compartment (Figure 10-3).

Figure 10-2

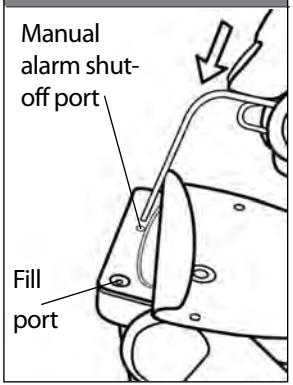
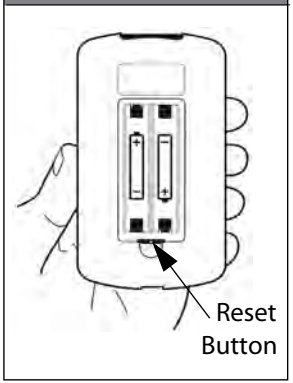


Figure 10-3



CHAPTER 11

Communication Failures

The Communication Process

When you turn on or use the Personal Diabetes Manager (PDM), it establishes communication with the active Pod. Usually, communication occurs quickly. Occasionally, communication takes longer and the PDM displays the communication icon during that time in the upper left-hand corner of the current screen.

However, if communication does not work, the PDM will walk you through the necessary steps to re-establish communication.

Communication can fail if the PDM is:

- Too far from the Pod—The PDM and Pod should be side by side while priming during activation.
- Interrupted by outside interference—See the "OmniPod System Notice Concerning Interference" in the Appendix.

As a safety feature, the communication distance between the Pod and PDM is reduced during activation. Once a Pod is primed and communicates with the PDM, the full communication range is restored and the Pod can receive commands only from that PDM.

Failure During Pod Activation or Operation

When you send an instruction from the PDM—such as **Start** to begin bolus delivery or **Enable** to begin using a different basal program—the Pod usually responds quickly. However, if the PDM cannot send your instruction within a few seconds, it displays the "Communication error" screen (Figure 11-1 on the next page).

1. Move the PDM closer to the Pod. The PDM will try to communicate with the Pod again. If communication still fails, you will see the message in Figure 11-2 on the next page.

Figure 11-1

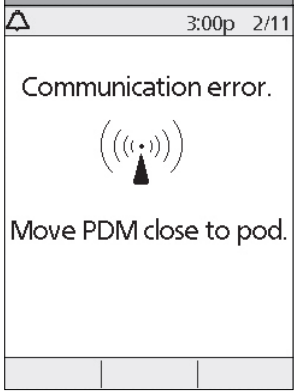


Figure 11-2

Figure 11-3

Figure 11-4

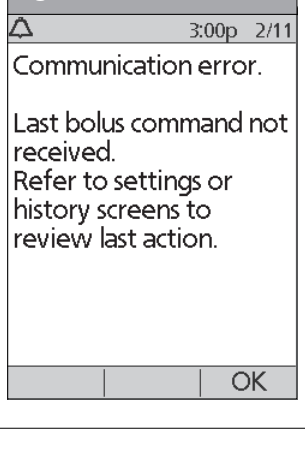
2. Move across the room or to a different room. Then press **Retry**.
   a. If you press **Retry** within 2 minutes, the PDM tries to communicate with the Pod again. If it cannot communicate, it displays the same screen as in Figure 11-2, then finally the "Communication time-out" screen (Figure 11-3). Press **OK** to check the Pod status.
   b. If the status check fails, you will see the screen in Figure 11-4. Press **OK** to try checking Pod status again or press **Discard** to begin the deactivation process.

3. If at any point in this process the PDM can communicate again with the Pod, you will see either:
   a. Figure 11-5, indicating that your original instruction or command was successfully sent to the Pod. When you press **OK**, or within 5 seconds, the System displays the next screen in the command sequence you were entering.
   b. Figure 11-6, indicating that your last command was not sent to the Pod. Press **OK**.

      If you were activating a Pod, the System returns to the previous screen where you can continue activation. If you were issuing any other command, the System returns to the **Status** screen, where you can reissue the command.

Figure 11-5

Figure 11-6


3:00p 2/11
Communication error.
Last bolus command not received.
Refer to settings or history screens to review last action.
OK

n Failure During Pod Deactivation

To review the deactivation process, see "Deactivate the current Pod" in Chapter 5, Using the Pod.

If you press **Confirm** to deactivate the active Pod and the PDM cannot send your instruction to the Pod, you will see the screen in Figure 11-7.

Figure 11-7

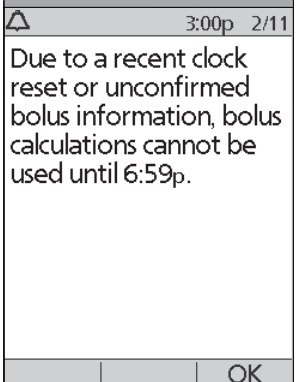
Either:

1. Press **Retry** to try deactivating the Pod again. If the PDM still cannot send the instruction, you will see Figure 11-7 again. Follow step 2.

2. Press **Discard**. The PDM will consider the Pod lost and ask whether you want to activate a new Pod.

NOTE If you have an unconfirmed correction bolus when you discard a Pod, then the bolus calculator will be temporarily disabled. In this situation, the bolus calculator is disabled until the duration-of-insulin-action period passes (Figure 11-8). If you have any questions, call Customer Care.

Figure 11-8



n Failure During Request for Status

If you turn on the PDM or press **Status** and the PDM cannot communicate with the Pod, it displays a communication icon (Figure 11-9). Below the icon is a soft key labeled **Skip**.

Either:

1. Wait until you see the "Pod status not available" screen (Figure 11-10).

Figure 11-9

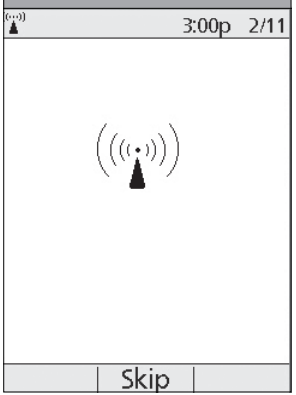
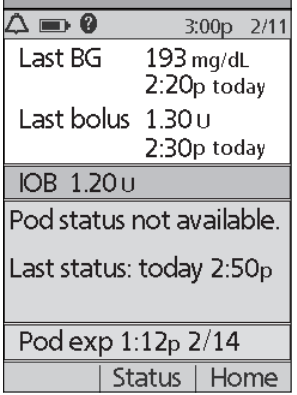


Figure 11-10

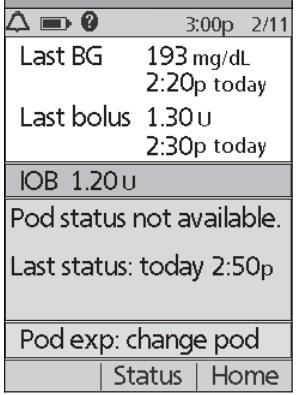


Or:

2. Press **Skip** to skip the communication process and immediately bring up Figure 11-10.

NOTE If the Pod has expired, you will see the screen in Figure 11-11 instead.

Figure 11-11



At either "Pod status not available" screen, press **Home** to return to the **Home** screen or press **Status** to send another status request.

Failure During Bolus Cancellation

When you instruct the PDM to cancel a bolus, if the PDM cannot send your instruction to the Pod within a few seconds, it displays the "Communication error" screen (Figure 11-12).

Figure 11-12

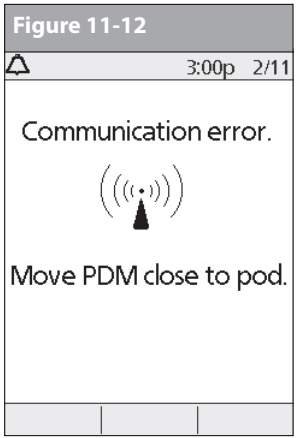
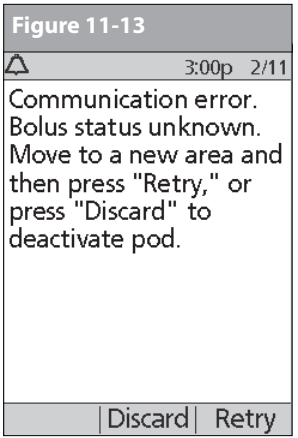


Figure 11-13


3:00p 2/11
Communication error.
Bolus status unknown.
Move to a new area and then press "Retry," or press "Discard" to deactivate pod.
Discard
Retry

1. Move the PDM close to the Pod. The PDM tries to communicate with the Pod again.
2. If the PDM still cannot communicate with the Pod, you will see the "Bolus status unknown" message (Figure 11-13).

If your PDM is damaged or not working as expected, call Customer Care for assistance. Be sure to check your blood glucose frequently. Remove your Pod and contact your healthcare provider for treatment guidelines to follow after you remove it.

3. Move across the room or to a different room. Then either:
   a. Press **Discard** to begin the deactivation process.
   b. Press **Retry** to repeat the attempts to communicate with the Pod. The PDM tries to communicate with the Pod again. If it cannot communicate, it displays the same screen as in Figure 11-13, then finally a second "Bolus status unknown" screen (Figure 11-14). Press **OK** to check the Pod status or press **Discard** to begin the deactivation process.
4. If at any point in this process the PDM can communicate again with the Pod, you will see Figure 11-15. The message indicates that your original instruction to cancel the bolus was successful.
   a. Press **OK**. The PDM displays the screen in Figure 11-16, showing how much insulin was delivered before the bolus was canceled.
   b. Press **OK** again to return to the **Status** screen.

Figure 11-14

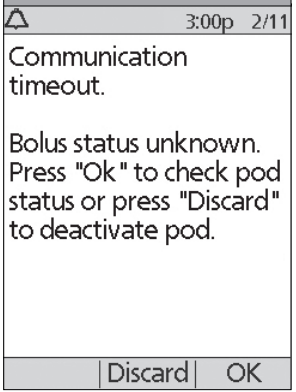
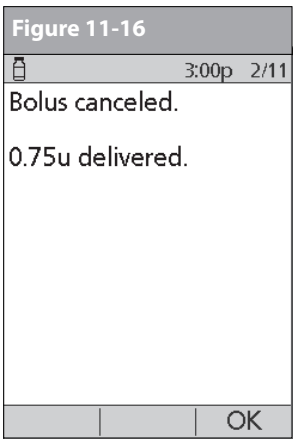

3:00p 2/11
Communication timeout.
Bolus status unknown. Press "Ok" to check pod status or press "Discard" to deactivate pod.
Discard
OK

Figure 11-15

Figure 11-16



Appendix

NOTE The OmniPod® Insulin Management System has no user-serviceable parts. If you require assistance operating or maintaining the System, please call Customer Care.

Pod Care and Maintenance

Storage

Store unopened Pods in a cool, dry place. Extreme heat or cold can damage Pods and cause them to malfunction. If Pods are exposed to extreme temperatures, inspect them carefully before use. Pods are sterile unless packaging is opened or damaged. Do not apply or use a Pod if its sterile packaging is opened or damaged.

Cleaning

Pods are waterproof. If you need to clean a Pod, you can gently wash it with a clean, damp cloth. Or you can use mild soap and water. However, do not use strong detergents or solvents. They can damage the Pod's casing or irritate the *infusion site*.

⚠ Hold the Pod securely and take care while cleaning it, so the cannula doesn't kink and the Pod doesn't become detached from your skin.

Personal Diabetes Manager Care and Maintenance

Storage

When you are not actively using the Personal Diabetes Manager (PDM) to enter or change programs, you can store it in a convenient, nearby location. The storage location should be cool and dry.

⚠ Do not store or leave the PDM where it may be exposed to extreme temperatures, such as inside a car. Extreme heat or cold can cause the device to malfunction.

If the PDM is not safe from children or others who may press the buttons by accident, consider using the optional **PDM lock** safety feature to prevent accidental program changes (see Chapter 6, Using the Personal Diabetes Manager).

Cleaning and disinfecting

Cleaning is to keep free from dirt, stains, or impurities; unsoiled. Disinfecting is the process of destroying pathogenic organisms or rendering them inert.

Keep your PDM test strip port and USB port free of debris and liquids. Dirt, dust, blood, and control solution can impair the functionality of your PDM or damage it.

If the battery compartment becomes soiled, gently shake out the debris or use a dry, lint-free cloth to remove it.

Do NOT use IV Prep wipes, alcohol wipes, soap, detergent, or solvents. Never put any liquid into the battery compartment. The PDM is NOT waterproof. Do NOT immerse it or place it in or near water.

If the meter is being operated by a second person who is providing testing assistance to the user, the meter should be disinfected prior to use by the second person.

Users should wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

Use the guidelines below to clean or disinfect your PDM:

The PDM can be cleaned and disinfected up to twice a week over the course of the life of the device (4 years). The PDM should be cleaned and disinfected at least once a week. In addition to cleaning and disinfecting once per week the device can withstand additional cleaning steps of up to 2 times per week over the 4 year use life.

1. Be sure to turn off your PDM before cleaning or disinfecting.
2. To clean and disinfect the outside surfaces of the PDM housing, use Dispatch® Hospital Cleaner Disinfectant Towels with Bleach (EPA Reg. No. 56392-8) (available online through major retailers).
3. Following the instructions on the label of the Dispatch® Hospital Cleaner Disinfectant Towels with Bleach (EPA Reg. No. 56392-8), wipe the outside surfaces of your PDM for at least one (1) minute. Treated surfaces must remain wet for a full two (2) minutes.

   NOTE While cleaning, do NOT allow debris or liquid to get into the test strip port, USB port, battery compartment, or buttons (see Figure A-1 on the next page).

4. Let your PDM air dry completely before checking your BGnext. We recommend you perform a control solution test to ensure the System functions properly. See "Performing a Control Solution Test" in Chapter 7, Checking Your Blood Glucose.
5. If you see any signs of deterioration of the PDM (i.e. cracking separation, discolorations.) Please contact Customer Care.

Figure A-1

Replacing Batteries

The PDM requires two (2) AAA alkaline batteries. You can purchase them at any grocery, hardware or convenience store.

AAA alkaline batteries are the preferred battery to power the PDM. Do not use any other type of batteries. Never use old or used batteries; the PDM may not work properly. Using any kind of batteries other than alkaline may reduce battery life and cause damage to the PDM.

On average, a pair of batteries powers the PDM for 3 weeks. The battery life indicator on the PDM shows the battery power level. See "Personal Diabetes Manager Icons" later in this Appendix for the various battery power levels and their respective icons.

The PDM automatically alerts you when its battery power gets low (see Figure A-2). When you see the "Low PDM battery" alert, press **OK** to turn off the alert. Replace the batteries as soon as you can.

Figure A-2

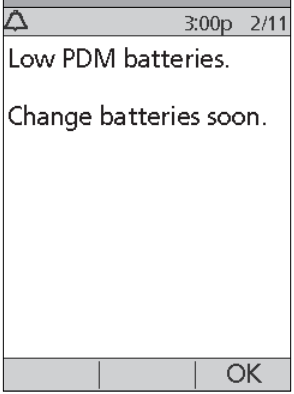


Figure A-3

When your PDM alerts you that battery power is getting low, the PDM will maximize remaining battery life by:

- Turning off your vibration alert (if set)
- Disabling bright mode
- Disabling the test strip port light

Once the batteries are replaced, these functions resume.

If the batteries run out, date and time are at risk. DO NOT remove the old batteries until you have new ones at hand. The PDM protects date and time for up to 2 hours after the batteries run out or are removed.

To replace batteries

1. Open the battery compartment on the back of the PDM by pushing the compartment latch inward and then upward (Figure A-3 on previous page). No special tools are necessary.
2. Insert 2 new AAA alkaline batteries into the compartment.

   The diagram inside the compartment shows you which direction to insert the batteries.
3. Replace the battery door.
4. Turn the PDM face up. The PDM powers on automatically.

The PDM is now ready to use. Dispose of the old batteries in accordance with local waste disposal regulations.

If the PDM becomes submerged in water

The PDM is not waterproof. Do not place it in water or leave it near water where it can accidentally fall in. If it becomes submerged in water:

1. Dry the outside of the PDM with a clean, lint-free cloth.
2. Open the battery compartment; remove the batteries and discard them.
3. Use a clean, lint-free cloth to gently absorb any water in the battery compartment.
4. Leave the battery compartment door open until the PDM is thoroughly dry.

Never use a blow dryer or hot air to dry the Pod or PDM. Extreme heat can damage the electronics.

5. Do not put in fresh batteries or attempt to use the PDM until it has thoroughly air-dried.

If you drop the PDM

The PDM is built to withstand reasonable amounts of abuse, but shock or a severe impact can damage it. If you drop the PDM or if it is otherwise subjected to severe impact:

1. Inspect the outside of the PDM for visible signs of damage.
2. Press and hold the **Power** button to see whether the PDM turns on and whether the LCD screen is damaged.
3. Inspect the inside of the battery compartment for visible signs of damage.
4. Do NOT use the PDM if it appears damaged or is not working as it should.

If you are unable to use your PDM to check your BG, have a back up meter on hand to check your BG.

If your PDM is damaged or not working as it should, please call Customer Care for assistance. Be sure to check your blood glucose frequently. Remove your Pod and contact your healthcare provider for treatment guidelines to follow after you remove it.

If you require assistance, please call Customer Care.

n Storage and Supplies

Store all OmniPod System products and supplies (including unopened Pods) in a cool, dry place. Products or supplies that have been exposed to extreme temperatures may not function properly.

It is especially important to store your *insulin* in a well-controlled environment. Inspect insulin before using it; never use insulin that looks cloudy or discolored. Insulin that is cloudy or discolored may be old, contaminated or inactive. Check the insulin manufacturer's instructions for use and expiration date.

To order all OmniPod System products and supplies, call Customer Care.

n Suggested Bolus Calculator Examples and Guidelines

A suggested bolus is equal to the sum of a correction bolus and meal bolus, then adjusted for insulin on board, if applicable. Examples of each of these elements are shown below.

Example of correction bolus

Target BG: 100 mg/dL
Current BG: 200 mg/dL
Correction factor (CF): 50

200 mg/dL (current) – 100 mg/dL (target) = 100 mg/dL

100 mg/dL ÷ 50 (CF) = 2 units *correction bolus*

If the *reverse correction* feature is turned **On** and if your current BG is below your target BG, the suggested bolus calculator subtracts a correction amount from the meal bolus.

Example of reverse correction bolus:

Target BG: 100 mg/dL
Current BG: 75 mg/dL
Correction factor (CF): 50

75 mg/dL (current) – 100 mg/dL (target) = –25 mg/dL

–25 mg/dL ÷ 50 CF = –0.5 units reverse correction bolus (reduces meal bolus)

Meal bolus calculation

Carbs entered ÷ insulin-to-carb (IC) ratio

Example of meal bolus

Carbs entered: 45 grams of carb
Insulin-to-carb ratio: 15

45 carbs ÷ 15 IC ratio = 3 units meal bolus

Insulin-on-board (IOB) calculation

(*Duration of insulin action* – time since your previous bolus) ÷ (duration of insulin action) ∗ (previous bolus)

IOB from a previous correction bolus is called "correction IOB," and IOB from a previous meal bolus is called "meal IOB."

Example of correction insulin-on-board (IOB)

Duration of insulin action: 3 hours
Time since previous correction bolus: 1 hour
Previous correction bolus: 3 units

3 hours – 1 hour = 2 hours

2 hours ÷ 3 hours = 2/3

2/3 ∗ 3 units = 2 units correction IOB

In other words, one hour after your previous correction bolus, you have received only 1 unit of insulin from it; 2 units of insulin are still working to correct your BG. This feature prevents delivering too much insulin when correcting a high BG.

Example of meal insulin-on-board (IOB)

Duration of insulin action: 3 hours
Time since previous meal bolus: 2 hours
Previous meal bolus: 4.5 units

3 hours – 2 hours = 1 hour

1 hours ÷ 3 hours = 1/3

1/3 * 4.5 units = 1.5 units meal IOB

In other words, two hours after your previous meal bolus, you have received 3 units of insulin from it; 1.5 units of insulin are still working to cover your meal.

Meal IOB is only used to reduce a correction bolus, and the correction bolus is only reduced until it becomes 0 units.

Examples of suggested bolus calculations

The examples below use these settings:

- Target BG: 100 mg/dL
- IC ratio: 1:15
- Correction factor (CF): 50
- Duration of insulin action: 3 hrs

Example 1

Current BG level: 150 mg/dL
Carb intake: 0 grams of carbohydrate (carbs)
Meal IOB: 1 unit

Correction insulin on board (IOB): 1 unit

Correction bolus: 150 mg/dL (current) – 100 mg/dL (target) = 50

50 ÷ 50 (CF) = 1 unit

Meal bolus: 0 (carbs) ÷ 15 (IC ratio) = 0 units

Suggested bolus dose = 1 (correction) + 0 (meal) – 2 (IOB) = 0U

Example 2

Current BG level: 150 mg/dL
Carb intake: 45 carbs
Meal IOB: 0 units
Correction IOB: 0 units

Correction bolus: 150 mg/dL (current) – 100 mg/dL (target) = 50

50 ÷ 50 (CF) = 1 unit

Meal bolus: 45 (carbs) ÷ 15 (IC ratio) = 3 units

Suggested bolus dose = 1 (correction) + 3 (meal) – 0 (IOB) = 4U

Example 3

Current BG level: 100 mg/dL
Carb intake: 45 carbs
Meal IOB: 1 unit
Correction IOB: 0 units

Correction bolus: 100 mg/dL (current) – 100 mg/dL (target) = 0

0 ÷ 50 (CF) = 0 units

Meal bolus: 45 (carbs) ÷ 15 (IC ratio) = 3 units

Suggested bolus dose = 0 (correction) + 3 (meal) – 0 (IOB) = 3U

Meal IOB is never subtracted from another meal bolus—only from a correction bolus.

Example 4

Current BG level: 150 mg/dL
Carb intake: 60 carbs
Meal IOB: 0 units
Correction IOB: 1 unit

Correction bolus: 150 mg/dL (current) – 100 mg/dL (target) = 50

50÷ 50 (CF) = 1 unit

Meal bolus: 60 (carbs) ÷ 15 (IC ratio) = 4 units

Suggested bolus dose = 1 (correction) + 4 (meal) – 1 (IOB) = 4U

Calculator guidelines

When the suggested bolus calculator is turned **On**, the OmniPod System applies these guidelines to the suggested bolus doses:

- Suggested bolus doses are rounded down to the nearest 0.05U.
- If the total of the suggested bolus calculation (correction bolus plus meal bolus) is less than zero, the suggested bolus dose is 0.00U.
- The System will not suggest a bolus dose if your current blood glucose (BG) reading is below the minimum BG you have set for bolus calculation (see Chapter 2, Getting Started, and Chapter 6, Using the Personal Diabetes Manager).
- The System suggests a correction bolus only when your BG reading is above the *correction threshold* or correct-above value you have set (see Chapter 2, Getting Started, and Chapter 6, Using the Personal Diabetes Manager).
- Meal IOB, which is insulin on board from a previous meal bolus, is subtracted first from the current correction bolus, if any, until it is zero. However, any remaining meal IOB is *never* subtracted from the current meal bolus.
- Correction IOB, which is insulin on board (active insulin) from a previous correction bolus, is then subtracted from the current correction bolus, if any remains, until it is zero. At that point, any remaining correction IOB is subtracted from the current meal bolus.
- The calculated insulin on board is rounded up to the nearest 0.05U.
- A reverse correction only occurs if the meal bolus is greater than 0.00U.
- If your blood glucose value is below the target blood glucose value and you have set *reverse correction* to **On,** the suggested correction bolus is subtracted from the suggested meal bolus. If you have set reverse correction to **Off**, the System will not subtract insulin from the suggested meal bolus dose.
- If you manually increase or decrease the suggested bolus, the following rules apply:
- If you increase a suggested bolus, the increase is applied to the meal bolus unless there is no meal bolus, in which case it is applied to the correction bolus.
- If you decrease a suggested bolus, the decrease is applied to the meal bolus until it reaches zero; then it is applied to the correction bolus. If there is no meal bolus, the decrease is applied to the correction bolus.

n OmniPod System Options and Settings

Time	12-hour or 24-hour clock
Date	MM/DD/YY DD/MM/YY MM.DD.YY DD.MM.YY YY.MM.DD YY-MM-DD
Maximum basal rate	30 U/hr Default is 3.00 U/hr
Basal programs	7
Basal rate segments	24 per program
Basal rate increment	0.05 units
Temp basal presets	7
Temp basal	%, Units, or Off 30 minutes to 12 hours in 30-minute increments Default is Off
Blood glucose (BG) goal for BG history	Upper and lower limits; 70 to 200 mg/dL in 1 mg/dL increments
Blood glucose reminder	On or Off; maximum of 4 active at any one time. Created at time of bolus entry; reminder can be set for 30 minutes to 4 hours after bolus is started, in 30-minute increments. Default is Off.
Blood glucose meter sound	On or Off Default is On
Suggested bolus calculator	On or Off Default is On
Target BG value and correction threshold	8 time segments; 70 to 200 mg/dL in 1 mg/dL increments
Minimum BG allowed for use by the suggested bolus calculator	50 to 70 mg/dL in 1 mg/dL increments Default is 70 mg/dL
Insulin-to-carb (IC) ratio	8 time segments; 1 to 150 g carb/U in 1g carb/U increments
Correction (sensitivity) factor	8 time segments; 1 to 300 mg/dL in 1 mg/dL increments
Reverse correction	On or Off Default is On
Duration of insulin action	2 to 6 hours in 30-minute increments
Bolus increment	0.05, 0.1, 0.5, or 1.0 units Default is 0.1 units
Maximum bolus size	30 units Default is 10 units
Extended bolus	%, Units, or Off 30 minutes to 8 hours in 30-minute increments Default is Off

Bolus presets	7
Carbohydrate presets	36
Suspend	30 minutes to 2 hours
Low reservoir volume indicator	10 to 50 units in 5-unit increments Default is 10.0 units
Pod expiration alert	1 to 24 hours in 1-hour increments Default is 4 hours
Auto-off alert	1 to 24 hours or Off in 1-hour increments Default is Off
PDM lock	On or Off Default is Off
History storage	5400 records/90 days
Language	English

n Pod Specifications

Size: 1.53" wide x 2.05" long x 0.57" high (3.9cm x 5.2cm x 1.45cm)

Weight (without insulin): 25 grams (0.88 oz)

Operating temperature range: Pod operating environment of 40°F – 98.6°F (4.4°C to 37°C).

Note: The Pod temperature will equilibrate to 73°F – 98.6°F (22.7° to 37°C) when worn on the body.

Startup temperature: above 50° F (10° C)

Storage temperature range: 32° F to 86° F (0° C to 30° C)

Reservoir volume (deliverable): 200 units

Cannula insertion depth: 6.5mm

Waterproof rating: IPX8 (25 feet for up to 60 minutes)

Insulin concentration: U-100

Alarm type: Audible

Operating relative humidity range: 20–85%, non-condensing

Storage relative humidity range: 20–85%, non-condensing

Operating atmospheric pressure: 696 hPA to 1060 hPA

Storage atmospheric pressure: 696 hPA to 1060 hPA

Non-pyrogenic: Fluid pathway only

Type BF Medical device: protection from electrical shock

Flow Capability:

Basal: Programmable by the user in 0.05U pulses up to 30.0 U per hour

Bolus:

- Rate: 1.5 units per minute
- Range: 0.05 to 30.0 units

Delivery accuracy (tested per IEC 60601-2-24):

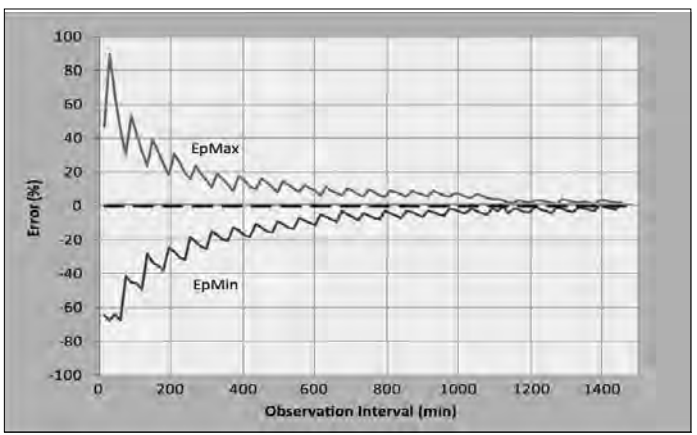
Basal: +/- 5% at rates > 0.05 U/hr
Bolus: +/- 5% for all set values > 0.05 units

n Accuracy Test Results

The following graph is designed to show flow accuracy of the Pod against given time periods.

Flow rate error

The following trumpet curve shows the accuracy of the delivery rate in relation to the observation period. The measurements were made using a Pod with a basal rate of 0.05 U/h at high operating temperature. The overall mean percentage flow error was 1.40%.



Personal Diabetes Manager Specifications

Size: 2.4" wide x 4.4" long x 0.98" high (6.21cm x 11.25cm x 2.5cm)

Weight (with batteries): 125 grams (4.41 oz)

Screen: 1.4" wide x 1.9" long (3.6cm x 4.8cm); 2.4" diagonal (6.1cm) LCD

Battery: Powered by 2 AAA alkaline batteries

Battery life: Approximately 3 weeks

Operating temperature range: 40° F to 104° F (4.4° C to 40° C)

Storage temperature range: -20.2° F to 140° F (-29° C to 60° C)

Operating relative humidity range: 20% to 90% non-condensing

Storage relative humidity range: 20% to 90% non-condensing

Operating atmospheric pressure: 696 hPA to 1062 hPA

Storage atmospheric pressure: 703 hPA to 1062 hPA

Communication distance: At start up the PDM and pod should be adjacent and touching, either in or out of tray to ensure proper communication during priming. At least 60" (152.40 cm) during normal operation.

Alarm type: Audible

Alert type: Audible and vibratory

Warranty: 4 Year Limited (PDM)

Blood Glucose Meter Specifications

Assay method: Coulometric electrochemical sensor

Calibration: Plasma equivalent

Hematocrit: 15% to 65%

Measurement units: mg/dL

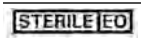
Result range: 20 to 500 mg/dL

Sample: Whole blood, capillary

Sample size: 300 nanoliters (0.3 microliters)

Test time: Results in as fast as 7 seconds

OmniPod System Label Symbols

Symbol	Meaning
	Do not reuse this device; single-use only
	Caution: Consult accompanying documents
	Refer to Instruction Manual
	Sterilized by ethylene oxide
	Manufacture date: (year–month)
	Lot number
	Expiration date (use-by date): (year–month)
	Reference/reorder number
	Device serial number
	Type BF medical device (protection from electrical shock)
	Manufacturer
	Non-pyrogenic; fluid pathway only
	Not MRI-safe
IPX8	Waterproof to 25 feet for up to 60 minutes
	Keep dry

Symbol	Meaning
	Storage temperature
	Do not use if package is damaged
Rx ONLY	Prescription home-use IVD

Personal Diabetes Manager Icons

Icon	Meaning	Icon	Meaning
	Power		More actions
	Bolus		Communication
	Pod change		Up/Down
	Diagnostics/ settings		Up/Down (on color)
	Temp basal		Status
	Suspend/cancel		Text entry right
	My Records		Submenu
	Advisory alarm		Home screen

Icon	Meaning	Icon	Meaning
	(Alternating) Hazard alarm		Insulin gauge
	Alert		Apply blood sample/ Blood glucose records
	PDM lock		Setup Wizard
	Battery 3/4 full		Battery full
	Battery 1/4 full		Battery half full
	Basal program		Battery empty
	"Lost" history record		User Information/ Support
	"Unconfirmed" history record		Blood Glucose Meter – Temperature out of range
	"Delivery Spans Midnight" history record		Active/default program or selected BG tag

n OmniPod System Notice Concerning Interference

The OmniPod Insulin Management System (both the Pod and the Personal Diabetes Manager or PDM) complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. These devices may not cause harmful interference.
2. These devices must accept any interference received, including interference that may cause undesirable operation.

Changes or modifications not expressly approved by Insulet could void the user's authority to operate the equipment.

Both the Pod and the PDM generate, use, and can radiate radio frequency energy, and may cause harmful interference to radio communications. There are no guarantees that interference will not occur in a particular installation. If the OmniPod System does cause harmful interference to radio and television reception, the interference may be corrected by one of the following measures:

- Move or relocate the OmniPod System.
- Increase the distance between the OmniPod System and the other device that is emitting or receiving interference.

Insulet Corporation declares that the OmniPod System is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. This ISM device complies with Canadian ICES-003 and IC-RSS-210.

n Electromagnetic Compatibility

The information contained in this section (such as separation distances) is, in general, specifically written with regard to the OmniPod System. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

General Notes

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the instructions for use.

Portable and mobile RF communications equipment can affect the function of medical electrical equipment.

Insulet Corporation declares that the OmniPod Insulin Management System is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.

Cables and accessories not specified within the instructions for use are not authorized. Using other cables and/or accessories may adversely impact safety, performance, and electromagnetic compatibility (increased emission and decreased immunity).

Care should be taken if the System is used adjacent to other electrical equipment; if adjacent use is inevitable, such as in work environments, the System should be observed to verify normal operation in this setting.

The System communicates by low level RF energy. As with all RF receivers, the potential for disturbance exists, even with equipment that complies with FCC and CISPR emissions requirements.

The OmniPod System communicates with the following characteristics:

Frequency: 433 Mhz, FSK modulation, with an effective radiated power of 13mW

The OmniPod System greatly exceeds the immunity requirements of the general standard for electromagnetic compatibility, IEC 60601-1-2.

Electromagnetic Emissions		
This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that is used in such an environment.		
Emissions	**Compliance according to**	**Electromagnetic environment**
RF Emissions (CISPR 11)	Group 2	The Pod and the PDM emit low level electromagnetic energy (RF) in order to communicate. Although unlikely, nearby electronic equipment may be affected.
CISPR B Emissions Classification	Class B	The System is suitable for use in all establishments including domestic establishments.

Electromagnetic Immunity			
The System is intended for use in the electromagnetic environment specified below. You should observe these requirements in the use of the System.			
Immunity against	**IEC 60601-1-2 test level**	**Compliance level (of this device)**	**Electromagnetic environment**
ElectroStatic Discharge, ESD (IEC 61000-4-2)	contact discharge: ± 6 kV air discharge: ± 8 kV	± 8 kV ± 15 kV	If floors are covered with synthetic material, try to avoid electrostatic discharges.
Power Frequency magnetic fields 50/60 Hz (IEC 61000-4-8)	3 A/m	400 A/m	Suitable for most environments. Magnetic field strengths in excess of 400 A/m would be unlikely except in close proximity to industrial magnetic devices.

Electromagnetic Immunity (Continued)			
Radiated RF (IEC 61000-4-3)	80 MHz–2.5 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the System than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter as below. Recommended separation distance: $d=1.17\sqrt{P}$ 150 KHz to 80 MHz $d=0.35\sqrt{P}$ 80 MHz to 800 MHz $d=0.7\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the System

You can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System, as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter, in watts	**Separation distance according to frequency of transmitter, in meters**		
	150 kHz to 80 MHz, d = 1.17 √P	*80 MHz to 800 MHz, d = 0.35 √P*	*800 MHz to 2.5 GHz, d = 0.7 √P*
0.01	0.12	0.035	0.070
0.1	0.37	0.11	0.22
1	1.17	0.35	0.7
10	3.70	1.11	2.21
100	11.7	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distances in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Customer Bill of Rights

Mission Statement

Insulet Corporation is dedicated to designing, developing, and distributing products that provide superior treatment options and lifelong health benefits for people with diabetes.

Scope of Services

Insulet Corporation's scope of services is limited to providing the OmniPod Insulin Management System. The System consists of the handheld, wireless Personal Diabetes Manager (PDM), which programs the Pod with insulin delivery instructions, and the compact, lightweight Pod, which is worn discreetly beneath clothing and delivers insulin based on instructions from the PDM. The PDM contains a fully integrated blood glucose meter and is very similar in materials, construction, and appearance to a personal digital assistant. The Pod features no tubing and virtually pain-free automated cannula insertion.

Compliance

The OmniPod Insulin Management System is manufactured and distributed by Insulet Corporation. The company is committed to complying with all federal and state regulations. If you have any questions or concerns regarding any of our activities, please contact us at 1-800-591-3455 (from outside the United States, 781-457-5098).

Supply Shipment

Insulet Corporation contacts customers to schedule quarterly supply shipments approximately two weeks prior to delivery.

Inquiries

Representatives are available to answer product-related inquiries 24 hours per day at our toll free number, 1-800-591-3455 (from outside the United States, 781-457-5098). For all other questions, concerns, or complaints, please contact us between the hours of 8:30am and 6:00pm Eastern Time, Monday through Friday, at 1-800-591-3455 (from outside the United States, 781-457-5098). We will respond immediately whenever possible; some issues may take up to 14 days to resolve.

CHAP Accredited

Insulet Corporation has been accredited by the Community Health Accreditation Program (CHAP) since 2007. To learn more about CHAP or to communicate concerns that you have been unable to resolve directly with the company, please visit www.chapinc.org or call CHAP at 800-656-9656.

Customer's Bill of Rights and Responsibilities

You have the right to:

1. Receive considerate and respectful service.
2. Receive service without regard to race, creed, national origin, sex, age, disability, sexual orientation, illness, or religious affiliation.
3. Expect confidentiality of all information pertaining to you, your medical care and service. Please review our HIPAA Privacy Notice later in this section.
4. Receive a timely response to your request for service.
5. Receive continued service.
6. Select the medical equipment supplier of your choice.
7. Make informed decisions regarding your care planning.
8. Understand what services will be provided to you.
9. Obtain an explanation of charges, including policy for payment.
10. Agree to or refuse any part of the plan of service or plan of care.
11. Voice complaints without fear of termination of service or other reprisals.
12. Have your communication needs met.

You have the responsibility to:

1. Ask questions about any part of the plan of service or plan of care that you do not understand.
2. Use the equipment for the purpose for which it was prescribed, following instructions provided for use, handling care, safety and cleaning.
3. Supply Insulet Corporation with insurance information necessary to obtain payment for services.
4. Be accountable for charges not covered by your insurance. You are responsible for settlement in full of your account.
5. Notify us immediately of:
   a. Equipment failure, damage or need of supplies.
   b. Any change in your prescription or physician.
   c. Any change or loss in insurance coverage.
   d. Any change of address or telephone number, whether permanent or temporary.

n Limited Warranty for the Personal Diabetes Manager

Limited Warranty Coverage

Insulet Corporation warrants to the original purchaser ("you") that the Personal Diabetes Manager (the "PDM") will be free from defects in materials and workmanship, under normal use and conditions, for a period of four (4) years from the date of purchase. If Insulet Corporation determines that the PDM is defective during the warranty period, Insulet Corporation will either repair or replace, at its option, the PDM at no charge to you, subject to the conditions and exclusions stated herein. This Warranty applies only to new devices and, in the event the PDM is repaired or replaced, the warranty period shall not be extended.

Warranty Claim Procedure

You must notify Insulet Corporation of the claimed defect within the warranty period by writing or calling: Insulet Corporation, 9 Oak Park Drive, Bedford, Massachusetts 01730; Telephone: 800-591-3455 (from outside the United States: 781-457-5098) and Fax: 877-467-8538. The claim must include the date of purchase, model number, serial number, and a description of the claimed defect. Insulet Corporation's authorization must be obtained prior to returning the PDM. If authorized, the PDM must be properly packaged and returned to Insulet Corporation. Insulet Corporation will pay all freight and transportation charges, where applicable, incurred in shipping a PDM to be repaired or replaced under this Warranty.

Conditions

Proof of Purchase in the form of a bill of sale or receipted invoice showing that the PDM is within the warranty period must be presented to obtain warranty service.

Exclusions

This Warranty covers only the original purchaser and cannot be transferred with sale, rental or other transfer of the PDM to any other person or entity.

THIS WARRANTY DOES NOT APPLY IF THE PDM HAS BEEN:

- changed or modified by any person or entity other than Insulet Corporation;
- serviced or repaired by any person or entity other than Insulet Corporation;
- damaged by an act of God, misuse, abuse, negligence, accident, wear and tear, unreasonable use, or by other causes unrelated to defective materials or workmanship.

Miscellaneous

REPAIR OR REPLACEMENT AS PROVIDED UNDER THIS WARRANTY IS YOUR EXCLUSIVE REMEDY. ANY APPLICABLE IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED IN DURATION TO THE DURATION OF THIS WARRANTY. IN NO EVENT SHALL INSULET CORPORATION, ITS SUPPLIERS, OR ITS DISTRIBUTORS BE LIABLE FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES FOR BREACH OF ANY EXPRESS OR IMPLIED WARRANTY ON THE PDM. Some states do not allow limitation on how long an implied warranty lasts, and some states do not allow the exclusion or limitation of consequential or incidental damages, so the above limitations or exclusions may not apply to you.

This Warranty gives you specific legal rights, and you may also have other rights which vary from state to state. This Warranty is valid only in the United States.

No Other Warranty

Unless modified in writing and signed by both parties, this Warranty is understood to be the complete and exclusive agreement between the parties, superseding all prior agreements, oral or written, and all other communications between the parties relating to the subject matter of this agreement. No employee of Insulet Corporation or any other party is authorized to make any warranty in addition to those made in this Warranty.

HIPAA Privacy Notice

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION IS USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO IT. PLEASE REVIEW IT CAREFULLY.

This notice of privacy practices (the "HIPAA Privacy Notice") describes how we may use and disclose your Medical Information to carry out treatment, payment, or health care operations and for other purposes that are permitted or required by law, including by the Health Insurance Portability and Accountability Act ("HIPAA") and all regulations issued thereunder. It also describes your rights to access and control your Medical Information. As used herein, "Medical Information" is information about you, including demographic information, that may identify you and that relates to your past, present, or future physical or mental health or condition and related health care services.

Uses and Disclosures of Medical Information

We will only use and disclose your Medical Information as permitted by law. Except for disclosures outlined in this HIPAA Privacy Notice and/or permitted by law, we will obtain your written authorization before using your Medical Information or disclosing it to any outside persons or organizations. You may revoke any written authorization you have provided to us at any time, except to the extent that we have made any uses or disclosures of your Medical Information in reliance on such authorization. To revoke a previously issued authorization, please send your request in writing, along with a copy of the authorization being revoked, to our Privacy Officer. If a copy of the applicable authorization is not available, please provide a detailed description and date of the same to our Privacy Officer.

There are some situations in which we may use or disclose your Medical Information without your prior written authorization, as described further below.

Uses and Disclosures of Your Medical Information Related to the Treatment and Services Provided by Us

Treatment, Payment, and Health Care Operations: We may use your Medical Information for treatment, to obtain payment for treatment, for administrative purposes, and to evaluate the quality of care that you receive without your authorization. We may use or disclose Medical Information about you without your authorization for several other reasons.

Example of Treatment: In connection with treatment, we may use your Medical Information to provide you with one of our medical devices.

Example of Payment: We may use your Medical Information to generate a health insurance claim and to collect payment on invoices for services and/or medical devices provided.

Example of Health Care Operations: We may use your Medical Information in order to process and fulfill your orders and to provide you with customer service.

Appointment Reminder and Other Communications: We may use or disclose your Medical Information without your prior written authorization to provide you or others with, among other things: (i) appointment reminders; (ii) product/supply reorder notifications; and/or (iii) information about treatment alternatives or other health-related products and services that we provide.

Family, Friends, and Emergencies: If you require emergency treatment and we are unable to obtain your consent, we may disclose your Medical Information to a family member or relative who is involved in your care.

Marketing: We may use or disclose your Medical Information to provide you with marketing communications about the health-related products and services that we provide, and about products, services, treatment, or healthcare providers that may be of interest to you.

Additional Categories of Uses and Disclosures

Required by Law: We may use or disclose your Medical Information to the extent that applicable law requires the use or disclosure of such Medical Information. Where the use and/or disclosure of Medical Information is by law, the use or disclosure will be made in compliance with the law and will be limited to the relevant requirements of the law. You will be notified, as required by law, of any such uses or disclosures.

Public Health: We may disclose your Medical Information for public health activities and purposes to a public health authority that is permitted by law to collect or receive the information.

The disclosure will be made for the purpose of controlling disease, injury, or disability. We may also disclose your Medical Information, if directed by the public health authority, to a foreign government agency that is collaborating with the public health authority.

Communicable Diseases: We may disclose your Medical Information, if authorized by law, to a person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading the disease or condition.

Health Oversight: We may disclose Medical Information to a health oversight agency for activities authorized by law, such as audits, investigations, and inspections. Oversight agencies seeking this information include government agencies that oversee the healthcare system, government benefit programs, other government regulatory programs, and civil rights laws.

Food and Drug Administration: We may disclose your Medical Information to a person or company as directed or required by the Food and Drug Administration: (i) to report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations; (ii) to track FDA-regulated products; (iii) to enable product recalls,

repairs, or replacement, or lookback (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of lookback); or (iv) to conduct post-marketing surveillance.

Legal Proceedings: We may disclose your Medical Information in the course of any judicial or administrative proceeding, in response to an order of a court or administrative tribunal (to the extent such disclosure is expressly authorized), in certain conditions in response to a subpoena, discovery request, or other lawful process.

Law Enforcement: We may disclose Medical Information, as long as applicable legal requirements are met, for law enforcement purposes. These law enforcement purposes include: (i) legal processes otherwise required by law; (ii) limited information requests for identification and location purposes; (iii) pertaining to victims of a crime; (iv) suspicion that death has occurred as a result of criminal conduct; (v) in the event that a crime occurs on the premises of the practice; and (vi) medical emergency in which it is likely that a crime has occurred.

Research: We may disclose your Medical Information to researchers when their research has been approved by an institutional review board that has reviewed the research proposal and established protocols to ensure the privacy of your Medical Information.

Criminal Activity: Consistent with applicable federal and state laws, we may disclose your Medical Information if we believe the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. We may also disclose Medical Information if it is necessary for law enforcement authorities to identify or apprehend an individual.

Military Activity and National Security: When the appropriate conditions apply, we may use or disclose Medical Information of individuals who are Armed Forces personnel: (i) for activities deemed necessary by appropriate military command authorities; (ii) for the purpose of a determination by the Department of Veterans Affairs of your eligibility for benefits; or (iii) to foreign military authority if you are a member of that foreign military service. We may also disclose your Medical Information to authorized federal officials for conducting national security and intelligence activities.

Workers' Compensation: We may disclose your Medical Information as authorized to comply with workers' compensation laws and other similar, legally established programs.

Inmates: We may use or disclose your Medical Information if you are an inmate of a correctional facility and your physician created or received your Medical Information in the course of providing care to you.

Required Uses and Disclosures: Under the law, we must make disclosures to you when required by the Office for Civil Rights, U.S. Department of Health and Human Services to investigate or determine our compliance with the requirements of HIPAA.

Nonidentifiable Information: We may use or disclose your Medical Information if we have removed from it any information that is personally identifiable to you.

Your Rights

The following is a statement of your rights with respect to your Medical Information and a brief description of how you may exercise these rights.

You Have the Right to Inspect and Copy Your Medical Information: This means you may inspect and obtain a copy of Medical Information about you, provided, however, that applicable law may limit your ability to inspect or copy certain types of records. In certain circumstances, if we deny your request to review Medical Information, you may have a right to have this decision reviewed. If you would like to make a request to review your Medical Information, please download our Request Form at

http://www.myomniPod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

and follow the directions included on that form.

We will respond to your request in a reasonable amount of time. If your request is honored, we may charge a nominal fee for photocopying expenses. Please contact our Privacy Officer if you have questions about access to your Medical Information.

You May Have the Right to Amend Your Medical Information:

If you believe that the Medical Information we have about you is incorrect or incomplete, you may ask us to make an amendment to your Medical Information. You may request an amendment as long as the Medical Information is still maintained in our records. If you would like to make a request to review your Medical Information, please download our Request Form at

http://www.myomniPod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

and follow the directions included on that form.

We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting an amendment to your Medical Information

You Have the Right to Request a Restriction of Your Medical Information: You may ask us not to use or disclose any part of your Medical Information for the purposes of treatment, payment, or healthcare operations. You may also request that any part of your Medical Information not be disclosed to family members or friends who may be involved in your care or for notification purposes as described in this HIPAA Privacy Notice.

Your request must state the specific restriction requested and to whom you want the restriction to apply. We are not required to agree to a restriction that you may request, but if we do agree to the requested restriction, we may not use or disclose your Medical Information in violation of that restriction unless it is needed to provide emergency treatment. If you would like to request a restriction of the use of your Medical Information, please download our Request Form at

http://www.myomniPod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

and follow the directions included on that form.

We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting a restriction of the use of your Medical Information.

You Have the Right to Request to Receive Confidential Communications from Us by Alternative Means or at an Alternative Location: We will accommodate reasonable requests to receive confidential communications from us by alternate means or at an alternative location. We may also limit this accommodation by asking you for information as to how payment will be handled or specification of an alternative address or other method of contact. We will not request an explanation from you as to the basis for the request. Please make this request in writing to our Privacy Officer.

You Have the Right to Receive an Accounting of Certain Disclosures We Have Made, if any, of Your Medical Information: This right applies to disclosures for purposes other than treatment, payment, or healthcare operations as described in this HIPAA Privacy Notice. It excludes disclosures we may have made to you, for a facility directory, to family members or friends involved in your care, or for notification purposes. You have the right to receive specific information regarding these disclosures that occurred after April 14, 2003, or as otherwise provided for under applicable law. You may request a shorter time frame. The right to receive this information is subject to certain exceptions,

restrictions, and limitations. If you would like to request an accounting of certain disclosure of your Medical Information, please download our Request Form at

http://www.myomniPod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

and follow the directions included on that form.

We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting an accounting of the disclosures of your Medical Information.

Our Duties

Generally: We are required by law to maintain the privacy and security of your Medical Information and to provide you with notice of our privacy practices with respect to Medical Information.

Revisions and Modifications: We may change our HIPAA Privacy Notice at any time. Before we make a significant change in our policies, we will change this HIPAA Privacy Notice and post our new notice (the "Revised HIPAA Privacy Notice"). We are required to abide by the terms of this HIPAA Privacy Notice until a Revised HIPAA Privacy Notice becomes effective. The Revised HIPAA Privacy Notice will be effective for all Medical Information that we maintain as of the effective date of the Revised HIPAA Privacy Notice even if we collected or received the Medical Information prior to the effective date of the Revised HIPAA

Privacy Notice. The current HIPAA Privacy Notice is posted on our Web sites at:

Insulet.com

MyOmniPod.com

You can also request a hard copy of the HIPAA Privacy Notice at any time by contacting our Privacy Officer.

What To Do If You Have a Problem or Question

If you have any questions relating to this HIPAA Privacy Notice or if you have a problem or complaint, please contact us by writing to:

Insulet Corporation
Attn: Privacy Officer
9 Oak Park Drive
Bedford, MA 01730

Furthermore, if you believe that Insulet has violated your privacy rights with respect to your Medical Information, you have the right to file a complaint in writing with our Privacy Officer or with the Office for Civil Rights, U.S. Department of Health and Human Services at 200 Independence Avenue, S.W. Washington, D.C. 20201.

Effective Date: August 11, 2004; Revision Date: April 1, 2009

Glossary

A1c (see Hemoglobin A1c)

Advisory alarm
Notification by the PDM that a serious condition exists.

Aseptic technique
A method for maintaining sterilization and preventing contamination.

Basal program
One or more *basal rates* that together cover a 24-hour period from midnight to midnight.

Basal rate
A small base or background amount of *insulin* that is delivered, at a preset rate, continuously for a specified period of time. Basal rates are measured in units per hour (U/hr).

Basal segment (time segment)
The time period during which a specific *basal rate* is delivered.

BG goal
A range of *blood glucose levels* that you are trying to achieve during a certain period of the day. For example, you may want one BG goal before meals, a different BG goal two hours after meals, and yet another BG goal for bedtime.

Blood glucose (see glucose)

Blood glucose level
The amount of *glucose*, or sugar, in the blood.

Blood glucose meter
A device used to check blood *glucose* content.

Bolus dose
A dose of insulin taken to correct an elevated *blood glucose level* or to cover *carbohydrates* in a meal or snack.

Bolus preset
A *bolus dose* of insulin, in units, that can be assigned a custom name and preprogrammed into the PDM.

Calorie
A unit of measurement used to express the energy value of food. Calories come from carbohydrate, protein, fat, and alcohol.

Cannula
A small, thin tube inserted below the skin, which serves to introduce a liquid medication into the body.

Carbohydrate (carb)
One of the three main nutrients found in food. (The other two are *protein* and *fat*.) Foods that contain carbohydrates include starches, sugars, vegetables, fruits, and dairy products.

Carbohydrate counting
A method of meal planning based on counting the number of grams of carbohydrate in a given food.

Carb preset
A favorite food item, snack, or entire meal that can be assigned a custom name and preprogrammed into the PDM. You set the carbohydrate value (and, optionally, the fat, protein, fiber, and total calories) for each carb preset.

Complications (of diabetes)
Harmful effects of diabetes such as damage to the eyes, kidney, heart, blood vessels, nervous system, teeth and gums, feet, and skin.

Correction bolus
An amount of *insulin* taken to compensate for high *blood glucose levels*. The OmniPod System calculates the correction bolus by taking the difference between your current blood glucose level and your *target blood glucose value*, then dividing the result by your *correction factor*.

Correction factor (also known as sensitivity factor)
A value that indicates how much one unit of *insulin* will lower your *blood glucose*. For example, if your correction factor is 50, one unit of insulin will lower your blood glucose by 50 mg/dL.

Correction threshold
The *blood glucose level* above which you would like to take insulin to reduce an elevated blood glucose.

CSII (continuous subcutaneous insulin infusion)
Delivering insulin continuously under the skin ("*subcutaneously*") on a programmed schedule.

Dawn phenomenon
An early morning rise in *blood glucose level* caused by the normal release of hormones that block *insulin's* effect.

Diabetes Control and Complications Trial (DCCT)

A study by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), conducted from 1983 to 1993 in people with type 1 *diabetes*, which showed that good *blood glucose* control significantly helped prevent or delay diabetes *complications*.

Diabetes, diabetes mellitus

A condition characterized by *hyperglycemia* (high *blood glucose*) resulting from the body's inability to use *blood glucose* for energy. In type 1 diabetes, the pancreas no longer makes *insulin* and therefore blood glucose cannot enter the cells to be used for energy. In type 2 diabetes, either the pancreas does not make enough insulin or the body is unable to use insulin correctly.

Diabetic ketoacidosis (see Ketoacidosis)

Duration of insulin action

The length of time that certain types of *insulin* remain active and available in your body after a *bolus*. This duration can vary greatly depending on the type of insulin you take. Only use rapid-acting insulin with the OmniPod® Insulin Management System.

Extended bolus

A feature of the OmniPod System that allows a meal *bolus dose* to be given over an extended period of time.

Fat

One of the three main energy sources in food. (The other two are *carbohydrate* and *protein*.) Fat is a concentrated source of energy, providing 9 calories per gram. Foods high in fat include oils, margarine, salad dressings, red meat, and whole-milk dairy foods.

Fiber

The indigestible part of plant foods. Foods that are high in fiber include broccoli, beans, raspberries, squash, whole-rain bread, and bran cereal. Fiber is a type of *carbohydrate* but does not raise *blood glucose levels* as other carbohydrates do.

Food Library

The Food Library is for reference only. (Food references contained in the library cannot be populated and used for calculations.)

The OmniPod System includes a reference library of over 1,000 common food items. The library shows each item's carbohydrate, fat, protein, fiber, and calories for a single portion.

The items in the food library are derived from the USDA database, USDA National Nutrient Database for Standard Reference.

Glucose

A simple sugar (also known as dextrose) used by the body for energy. Without *insulin*, the body cannot use glucose for energy.

Hazard alarm
Notification by the PDM and Pod that a dangerous condition exists.

Healthcare provider
A professional who practices medicine or teaches people how to manage their health. All healthcare providers are a resource for valuable diabetes management information.

Hemoglobin A1c (HbA1c)

A test that measures a person's average *blood glucose level* over the past 2 to 3 months. Also called glycosylated hemoglobin, the test shows the amount of *glucose* that sticks to the red blood cell, which is proportional to the amount of glucose in the blood.

Hyperglycemia (high blood glucose)
A higher-than-normal level of *glucose* in the blood; generally 250 mg/dL or higher.

Hypoglycemia (low blood glucose)

A lower-than-normal level of *glucose* in the blood; generally 70 mg/dL or lower.

Hypoglycemia unawareness
A condition in which a person does not feel or recognize the symptoms of *hypoglycemia*.

Infusing
Introducing a liquid substance under the skin into the body.

Infusion site
A place on the body where an infusion set or Pod is placed and cannula is inserted.

Insulin
A hormone that helps the body use *glucose* for energy. The beta cells of a healthy pancreas make insulin.

Insulin on board (IOB) (active insulin)
The amount of *insulin* that is still "active" in the body from a previous *bolus* dose. In the OmniPod System, insulin on board (IOB) is considered in two parts: the Insulin on Board (IOB) from a previous *correction bolus* and the IOB from a previous *meal bolus*.

The amount of time insulin remains "on board" or "active" depends on each individual's *duration of insulin action*. Talk with your *healthcare provider* to determine your duration of insulin action.

The OmniPod System continually calculates the Insulin on Board (IOB) to help prevent "stacking" of bolus doses, which is a major cause of *hypoglycemia*.

Insulin reaction (see hypoglycemia)

Insulin-to-carbohydrate ratio (IC Ratio)
Number of grams of *carbohydrate* covered by one unit of *insulin*. For example, if your insulin-to-carbohydrate ratio is 1:15, then you need to deliver one unit of insulin to cover every fifteen grams of carbohydrate you eat.

In vitro
Literally, "in glass." Refers to a biological function taking place in a laboratory dish rather than in a living organism.

Ketoacidosis (diabetic ketoacidosis or DKA)
A very serious condition in which extremely high *blood glucose levels* and a severe lack of *insulin* cause the body to break down *fat* for energy. The breakdown of fat releases *ketones* into the blood and urine. DKA can take hours or days to develop, with symptoms that include stomach pain, nausea, vomiting, fruity breath odor, and rapid breathing.

It is important to rule out ketoacidosis when you experience symptoms that might otherwise indicate the flu.

Ketones
Acidic by-products that result from the breakdown of *fat* for energy. The presence of ketones indicates that the body is using stored fat and muscle (instead of *glucose*) for energy.

Meal bolus (also known as carbohydrate bolus)
An amount of *insulin* administered before a meal or snack to ensure that *blood glucose levels* stay within the desired BG goal after a meal. The OmniPod System calculates a meal bolus by dividing the grams of carbohydrates you are about to eat by your *insulin-to-carbohydrate ratio*.

Multiple daily injections (MDIs)
Introducing *insulin* into the body with a syringe several times a day.

Occlusion
A blockage or interruption in *insulin* delivery.

Prime bolus
An amount of *insulin* used to fill the *cannula*, preparing it to begin delivering insulin under your skin.

Protein
One of the three main energy sources in food (the other two are *carbohydrate* and *fat*). Protein is necessary for the growth, maintenance, and repair of body cells and tissues. Protein contains 4 calories per gram. Foods high in protein include meat, poultry, fish, legumes and dairy products.

Reverse correction (negative correction)

Using an individual's *correction factor (sensitivity factor)*, the reverse correction is a calculation that reduces a portion of a meal *bolus dose* when the patient's *blood glucose level* is below their *blood glucose target*. This feature is an option in the OmniPod® Insulin Management System, which should be turned on or off according to the advice of a *healthcare provider*.

Sensitivity factor (see correction factor)

Sharps

Any medical item that may cause punctures or cuts to those handling them. Sharps include needles, syringes, scalpel blades, disposable razors, and broken medical glassware. Dispose of used sharps according to local waste disposal regulations.

Sharps container

A puncture-proof container used for storage and disposal of used *sharps*.

Soft Key

A button on the PDM whose label or function appears on the screen directly above the button. The label changes depending on the task you are performing.

Subcutaneous

Under the skin.

Suggested bolus calculator

A feature that calculates bolus doses with user-specific settings and inputs. The settings used to calculate a suggested bolus are *target BG*, *insulin-to-carbohydrate (IC) ratio*, *correction factor* (CF) and *duration of insulin action*. The inputs used to calculate a suggested bolus are current BG, carbs entered, and *insulin on board*. The bolus calculator can be turned **Off** or **On** in the PDM.

Target blood glucose (BG) level

The ideal number at which you would like your *blood glucose level* to be. The OmniPod System uses this number in calculating *bolus doses*.

Temp basal

A *basal rate* that is used to cover predictable, short-term changes in basal *insulin* need. Temporary rates are often used during exercise and for sick-day insulin adjustments.

Temporary basal preset

An adjustment in a *basal rate*, in either % or U/hr, that can be assigned a custom name and preprogrammed into the PDM.

Time segment (see basal segment)

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My PDM Settings

Use this form to keep track of your important PDM settings. Remember to update your information as you change or add settings.

Basal Program 1	
Name _____	**Rate**
12:00 AM to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr

Basal Program 2	
Name _____	**Rate**
12:00 AM to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr
_____ to _____	_____ U/hr

Target BG		
Target BG for each time segment defined, starting at midnight. These values are used by the suggested bolus calculator.	**Target BG**	**Suggest correction when BG is above**
12:00 AM to _____	_____	_____ mg/dL
_____ to _____	_____	_____ mg/dL
_____ to _____	_____	_____ mg/dL
_____ to _____	_____	_____ mg/dL
_____ to _____	_____	_____ mg/dL
_____ to _____	_____	_____ mg/dL
_____ to _____	_____	_____ mg/dL
_____ to _____	_____	_____ mg/dL

Insulin-to-Carbohydrate Ratio	
Insulin-to-carbohydrate ratio for each time segment defined, starting at midnight.	**1 unit of insulin covers**
12:00 AM to _____	_____ g carb
_____ to _____	_____ g carb
_____ to _____	_____ g carb
_____ to _____	_____ g carb
_____ to _____	_____ g carb
_____ to _____	_____ g carb
_____ to _____	_____ g carb
_____ to _____	_____ g carb

My PDM Settings

Duration of Insulin Action	
Time that insulin will remain "active" in the body from a previous bolus.	_____ hrs

Correction Factor	
Correction factor for each time segment defined, starting at midnight.	**1 unit of insulin decreases BG by**
12:00 AM to _____	_____ mg/dL
_____ to _____	_____ mg/dL
_____ to _____	_____ mg/dL
_____ to _____	_____ mg/dL
_____ to _____	_____ mg/dL
_____ to _____	_____ mg/dL
_____ to _____	_____ mg/dL
_____ to _____	_____ mg/dL

Bolus Presets	
Name	**Units**
_____	_____ U
_____	_____ U
_____	_____ U
_____	_____ U
_____	_____ U
_____	_____ U
_____	_____ U

Temp Basal Presets	
Name	**Rate (circle measurement)**
_____	_____ U/hr or %
_____	_____ U/hr or %
_____	_____ U/hr or %
_____	_____ U/hr or %
_____	_____ U/hr or %
_____	_____ U/hr or %
_____	_____ U/hr or %

Carb Presets	
Name	**Grams of carbohydrate**
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb

My Notes

OmniPod®

Insulin Management System

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MyOmniPod.com

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Model: **UST400**

14421-AW Rev C